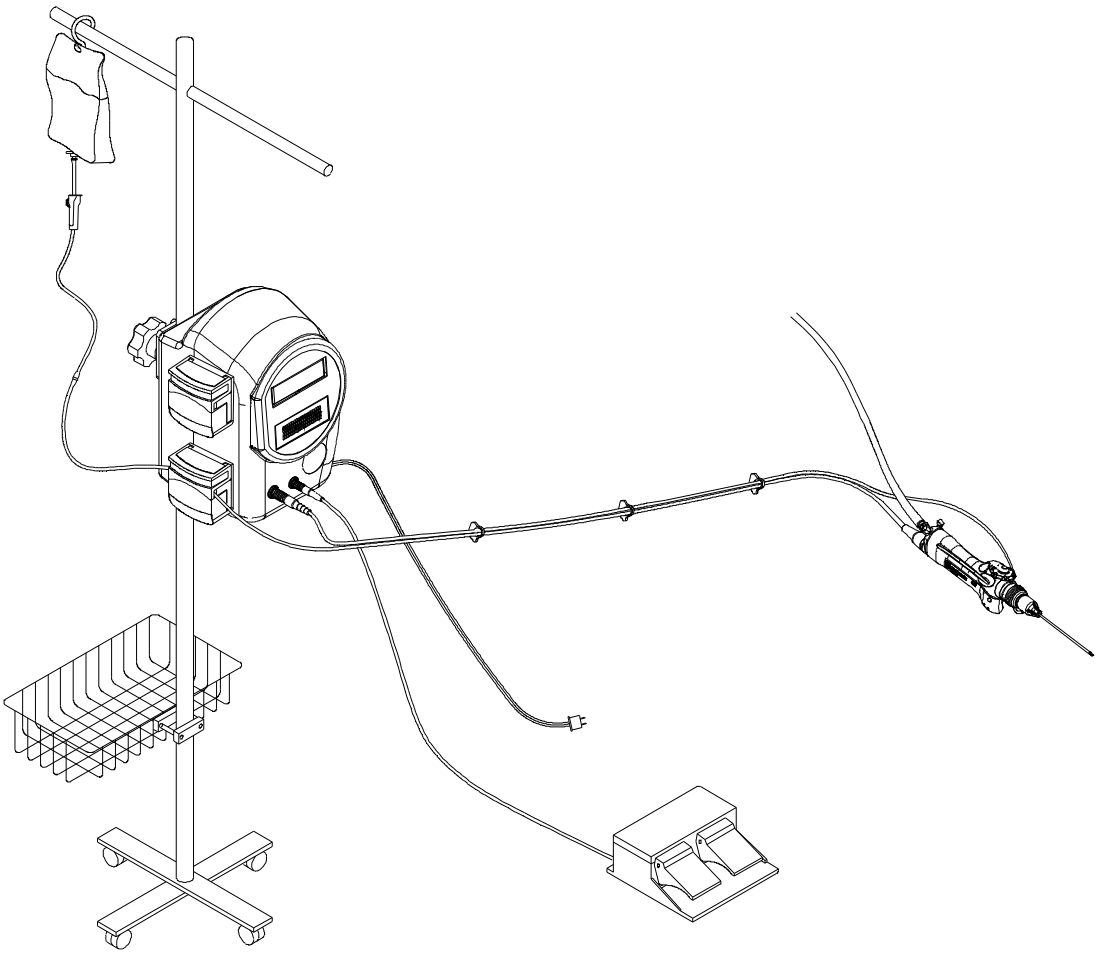
XPS® Model 3000 System

User's Guide



Medtronic
XOMED

Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, FL 32216-0980 U.S.A.

Authorized Representative (for EC regulatory matters)
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel.: 011-31-45-566-8000
Fax: 011-31-45-566-8668

Rx Only

™ are trademarks and ® are registered marks of Medtronic Xomed, Inc.

Copyright© 2005 Medtronic Xomed, Inc.
Made in U.S.A.

The information contained in this document was accurate at time of publication. Medtronic Xomed reserves the right to make changes in the product described in this manual without notice and without incorporating those changes in any products already sold.

TABLE OF CONTENTS

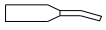
Symbols iii
When the System Arrives iv
Warnings and Precautions ..... iv-vi
Customer Service vii
Device Description 1
System Description 1
Indications 2
Contraindications 2
Parts List 3
XPS® 3000 Console Description 4
Front Console 4
Rear Console 5
XPS® 3000 Set-Up and Use 6
Cable Connections 6
Console Set-Up 6-7
Language Selection 6
XPS® Multifunction Footswitch, 1895400 10
XPS® Multifunction Footswitch, Single Pedal, 1895420 10
XPS® Single Function Footswitch, 1895410 10
XPS® StraightShot® M4 and Magnum® II Microdebrider System Set-Up and Use 11
Before Surgery 11-12
XPS® StraightShot® M4 and Magnum® II Handpiece Accessories 13
Blade or Bur Installation 14
Tubing Attachment 14
XPS® StraightShot® M4 and Magnum® II Surgical Precautions 14
After Surgery 15
Blade or Bur Removal 15
Visao™ and Xcalibur® Drill System Set-Up and Use 16
Before Surgery 18
Visao™ and Xcalibur® Bur Installation and Tubing Attachment 19
Bur Attachment 19
Curved Bur Installation 19
Tubing Attachment-Irrigation 19
Tubing Attachment-Cooling 20
Visao™ and Xcalibur® Surgical Precautions 20
Powerforma® Drill System Set-Up and Use 21
Before Surgery 22
Powerforma® Bur Installation and Tubing Attachment 23
Bur Attachment 23
Tubing Attachment-Irrigation 23
Powerforma® Surgical Precautions 23
Skeeter® Ultra-Lite Oto-Tool System Set-Up and Use 24
Before Surgery 26

Cleaning and Sterilization Guidelines 27
Precaution 27
Warnings 27
After Surgery 27-28
Cleaning 28-30
Sterilization 31-34
Warnings 31
Precautions 31
Sterilization References 34
Troubleshooting 35
System Malfunctions 35
Blade or Bur Malfunctions 35
Drill and Handpiece Malfunctions 36
Footswitch Malfunctions 36
Limited Warranty and Repair 37
Technical Specifications 38
Handpieces - XPS® StraightShot® M4 Microdebrider, StraightShot® Magnum® II, LandmarX® Magnum® II, XPS® StraightShot® III (Japan only) 38
Visao™ and Xcalibur® Drills 38-39
MPS® Powerforma® Drill 39
Skeeter® Ultra-Lite Oto-Tool 39
Console 39
XPS® Multifunction Footswitch, 1895400 40
XPS® Multifunction Footswitch, Single Pedal, 1895420 40
XPS® Single Function Footswitch, 1895410 40
Compliance 40
Guidance and manufacturer's declaration – electromagnetic immunity - Part I 41
Guidance and manufacturer's declaration – electromagnetic emissions 42
Recommended separation distances between portable and mobile RF communications equipment and the XPS® 3000 42
Guidance and manufacturer's declaration - electromagnetic immunity - Part II 43
Recommended Environmental Conditions 43

LIST OF FIGURES

Figure 1 Front Console 4
Figure 2 Rear Console 5
Figure 3-A Control Button Cluster-Standard Mode 7
Figure 3-B Control Button Cluster-Procedure Mode 7
Figure 4 Default Displays and Settings 8
Figure 5 Menu Flow Diangram 9
Figure 6-A XPS® Multifunction Footswitch, 1895400 10
Figure 6-B XPS® Multifunction Footswitch, Single Pedal, 1895420 10
Figure 7 XPS® Single Function Footswitch, 1895410 10
Figure 8 XPS® StraightShot® M4 and Magnum® II Microdebrider System 12
Figure 9 Blade or Bur Installation 14
Figure 10 Tubing Attachment 14
Figure 11 Xcalibur® Hi-Torque Drill System 16
Figure 12 Visao™ High-Speed Otologic Drill or Xcalibur® Hi-Speed Drill System 17
Figure 13 Powerforma® Drill System 21
Figure 14 Skeeter® Ultra-Lite Oto-Tool System 25

SYMBOLS

⚠	ATTENTION, SEE INSTRUCTIONS FOR USE
REF	CATALOG NUMBER
SN	SERIAL NUMBER
	DATE OF MANUFACTURE
	USE BY DATE
	DO NOT REUSE
STERILE EO	STERILIZED BY ETHYLENE OXIDE. DO NOT USE IF PACKAGE IS OPENED OR DAMAGED.
STERILE R	STERILIZED BY RADIATION. DO NOT USE IF PACKAGE IS OPENED OR DAMAGED.
LOT	LOT NUMBER
	ON (MAIN POWER)
	OFF (MAIN POWER)
	REVERSE
	FORWARD
	OSCILLATION
	FOOTSWITCH — VARIABLE MODE
	FOOTSWITCH — START/STOP
	FOOTSWITCH
	FOOTSWITCH DIRECTION - FORWARD
	FOOTSWITCH DIRECTION - OSCILLATE
	FOOTSWITCH DIRECTION - REVERSE
	TYPE B APPLIED PART
ACC	ACCESSORY CONNECTOR
	MANUAL START/STOP
	HANDPIECE
	SKEETER® HANDPIECE
	RF TRANSMITTER (INTERFERENCE MAY OCCUR)
	CAUTION: PINCH HAZARD. KEEP FINGERS CLEAR OF ROLLERS.

MENU	MENU
	IRRIGANT
	COOLANT
	PUMP
	LOCKED
	UNLOCKED

WHEN THE SYSTEM ARRIVES

UNPACKING AND INSPECTION

As the box is unpacked, check off the contents of the box against the items listed on the packing slip. If the contents are incomplete or if there is damage, notify Customer Service. If the shipping container is damaged, or the cushioning material shows signs of stress, notify the carrier as well.

Keep the shipping materials for carrier inspection.

After unpacking your new XPS® Model 3000 System, save the cartons and packing material. If the instrument is to be shipped from one location to another, the carefully designed shipping package will provide proper protection.

WARNINGS AND PRECAUTIONS

It is important that the XPS® Model 3000 operator be familiar with this manual: its precautions, procedures and safety issues. Three labels are used in this manual to identify important concerns, conditions, or procedures:

"WARNING"
Identifies conditions or practices that present a risk of injury to the patient and/or user.

"PRECAUTION / CAUTION"
Identifies conditions or practices that could result in damage to the equipment.

"NOTE"
Identifies special information allowing easier maintenance of equipment or to clarify or emphasize important instructions.

WARNINGS
- Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is replaced. Damaged parts may deposit metal shavings on surgical site.
- Do not modify accessories used with the handpiece. Performance could be diminished with modified accessories.
- Insertion of metal objects in blade or bur tip may cause the blade or bur to break leaving fragments in the wound. The fragments may be difficult to remove, causing irritation, inflammation and foreign-body response at surgical site.
- Do not use any parts other than Medtronic Xomed, Inc. system components as damage or substandard performance could result.
- Blade and bur accessories are available for resection of soft tissue and bone for surgical procedures. Use of accessories depends on the intended application and patient needs. Sharp-cutting powered accessories induce bleeding and removal of significant tissue and bone.
- Do not attach unapproved components to the XPS® 3000 Console to avoid electrical macro shock.
- Carefully inspect burs prior to and following each use for excessive wear, fragmentation, eccentricities or other defects. Do not use dull, damanged or bent burs. Use of dull burs can reduce the handpiece effectiveness and cause the handpiece temperature to increase.
- Do not attempt to resharpen used burs. Worn burs should be replaced with new ones frequently to ensure effective cutting and control of the drill.
- Excessive pressure applied to bur may cause bur fracture. Should a bur fracture during use, extreme care must be exercised to ensure that all fragments of the bur are retrieved and removed from the patient. Unremoved bur fragments may cause tissue damage to the patient.
- Test for bur wobble (eccentricity) at desired speed prior to use. Use a bur guard (Xcalibur only) if needed. Select a new bur or reduce speed if wobble is observed.
- Test for bur wobble (eccentricity) at the desired speed prior to use. Select a new bur or reduce speed if wobble is observed. Eccentricity of the bur can cause bur vibration and may result in excessive tissue and bone destruction and hearing damage. Always examine the operation of each bur in the handpiece before each use. Operating certain burs at high speed can cause vibration of the bur.
- Keep the cooling sleeve irrigated to prevent thermal injury to tissue.
- During procedures near nerves, keep bur and bur cannula away from tissue to minimize the potential for thermal injury.

WARNINGS (continued)

- For procedures near nerves, nerve monitoring should be used to alert the user of the potential for injury.
- Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using XPS® accessories. The use of powered reciprocating/rotating instruments may result in vibration-related injury. Use appropriate precautions.
- Employ visualization when using rotating XPS® accessories. Discontinue powered application in the event of lack of visualization of the surgical site.
- Use methods at the operative site to control bleeding that do not compromise patient safety during at-risk surgery.
- Use lock on StraightShot® M4 handpiece to prevent inadvertant rotation of blade or bur during use.
- When precise location of the blade tip is required, engage the rotation lock on the handpiece, then calibrate and verify the blade tip on the Image Guided Surgery (IGS) system. Always lock the StraightShot® M4 handpiece when driving non-rotatable blades to maintain their IGS calibration.
- Always keep the cutting tip of the accessory away from fingers and loose clothing. Prevent laceration of user and cross-contamination through compromised glove.
- Do not change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
- Bending or prying may break the blade or bur, causing harm to patient or staff.
- Discontinue use of curved bur if tip begins to wobble and replace bur to prevent unintended tissue removal from patient.
- Do not use burs above the speed indicated on the bur label. Exceeding speed may cause the burs to break.
- Disposable devices are for single-use only. Do not attempt to sterilize disposable devices. The disposables are packed sterile and not intended for repeat use. To prevent contamination use only once.
- Disconnect power to the XPS® 3000 Console before cleaning the unit to avoid electrical macro shock.
- After each procedure, properly clean all reusable system components.
- Sterilize and dry reusable device before storing the system. Decrease likelihood of cross-contamination with timely sterilization.
- Remove and discard accessories following local regulations for proper disposal of contaminated materials.
- Properly dispose of single-use devices removed from sterile packages. Devices lost sterility upon removal from packaging.
- All service must be performed by Medtronic Xomed-qualified personnel only.

WARNINGS BEFORE SURGERY

- Verify reusable device was sterilized prior to use. If not sterilized, do not use.
- Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination.
- Do not operate the XPS® 3000 System in the presence of flammable anesthetics. Avoid potential ignition or explosion of gases.
- Achieve electrical grounding reliability with proper connections. Connect the XPS® 3000 Console to hospital grade receptacles only.
- Use adequate irrigation from a separate user-provided irrigating source. The use of a bur without irrigation may cause an inordinate amount of heat buildup resulting in thermal injury to tissue.
- When not operating handpiece, ensure that handpiece rests on a non-conductive surface that provides containment for handpiece and blade/bur. Avoid unintended thermal injury by an uncontained handpiece.
- When not operating handpiece, eliminate accidental foot control activation. Control energy to and through handpiece to prevent unintended tissue, bone or nerve resection.
- This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for anesthetized patient.

PRECAUTIONS

- XPS® Blades should be operated in the oscillate mode only. Operating in the forward mode may cause damage to the blade. XPS® burs should be operated in the forward mode only.
- The handpiece should be evaluated prior to each use for suitable operating condition.
- System components should be operated and inspected for damage prior to use. Do not use system if damage is apparent.

PRECAUTIONS (continued)

- It is recommended that a secondary handpiece be available to minimize any downtime and inconvenience to the surgical staff.
- The StraightShot® Magnum® II and StraightShot® M4 Microdebriders are intended to operate at speeds greater than 6,000 rpm ONLY when used with the XPS® High Speed bur line.
- Always ensure that the bur is securely engaged into the handpiece prior to operating the system.
- When operating or testing the Poweforma®, Xcalibur® and Visao™ drill handpieces, ensure the bur is properly inserted and locked into the handpiece. Running the drill with the collet unlocked can damage the locking mechanism.
- Improper priming of the Xcalibur® and Visao™ Hi-Speed Drills will result in excessive handpiece temperature.
- The Xcalibur® and Visao™ High-Speed Water-Cooled Drills work only with the XPS® 3000. Use without water-bag will damage the motor in the handpiece.
- Do not allow the console or footswitch to get wet. If liquid enters the console or footswitch, damage could occur.
- To prevent damage to curved blades and burs, disconnect suction tube prior to changing blade or bur during procedure.
- DO NOT clean handpieces in ultrasonic cleaner or allow them to be fully immersed in any soaking solution. These procedures may result in damaging the handpieces beyond repair.
- Do not sterilize the console or footswitch.
- Do not clean the handpiece in an ultrasonic cleaner or cold soak sterilize the handpiece in glutaraldehyde. Do not immerse handpieces, motors, or handpiece cables in any solution, except as detailed in the Cleaning section of this manual. These procedures void the warranty and may damage the handpiece beyond repair.
- Always handle handpieces with care to avoid damage.
- Do not use organic solvents such as acteone or isopropyl alcohol to clean the bur chuck. Use only an enzymatic detergent and distilled water for cleaning after every case or as required.
- Remove the bur from the handpiece before sterilization.
- Sterilize immediately after cleaning. Do not store unless a drying cycle has been performed.
- Always wrap the electrical cord carefully inside the sterilization tray during sterilization to prevent damage to the cord when closing the tray lid.
- Remove the handpiece from the sterilizer immediately after the sterilization cycle is complete.
- Temperatures higher than those stated may be used for handpiece sterilization when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149°C (300ºF). Heating above 149°C (300ºF) may damage components and will void the warranty.
- Regardless of which type of steam sterilization is used, it is extremely important that the handpiece is rapidly and completely dried before it is stored. Do not operate or store the handpiece unless a drying cycle has been preformed. If a vacuum drying cycle is not used following steam sterilization, moisture may be trapped within the handpiece causing corrosion and residue deposits, resulting in premature wear and a reduction in the functional life expectancy of the handpiece. In addition, damage may result if the handpiece is operated with moisture in the electronic connections.
- Store system in a clean dry place.
- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- Use of accessories and cables other than those specified and sold by Medtronic Xomed may result in increased emissions and decreased immunity of this unit.
- The XPS® 3000 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the XPS® 3000 should be observed to verify normal operation in the configuration in which it will be used.

NOTICE

It is important that you read this entire manual before you use the XPS® Systems. It is unsafe to use these devices before you have read and are thoroughly familiar with this document.

CUSTOMER SERVICE

U.S. CUSTOMER SERVICE

General customer service and technical support are available toll-free:
800-874-5797 or 904-296-9600
Monday-Friday
8:00 AM - 6:00 PM E.S.T.
www.xomed.com

MICROELECTRONICS REPAIR

Technical Support:
800-872-9877
904-296-6448 (FAX)
Monday - Friday
8:00 AM - 5:00 PM E.S.T.

Return Address:
Medtronic Xomed, Inc.
4102 Southpoint Blvd.
Jacksonville, FL 32216-0980 U.S.A.
Attention: Repair Department

CUSTOMER SERVICE INFORMATION

For further information regarding the use of this product or to report any problems, please contact Medtronic Xomed using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

MEDTRONIC XOMED, INC. HELPLINE

Should you need immediate help with a technical question or guidance through the appropriate protocol, just call the Medtronic Xomed Help Line at **1-800-874-5797.**

NOTE:
When contacting our Customer Service and Technical Support, please have the appropriate product number, product serial number, date of purchase, and nature of inquiry available.

Product Number _____

Serial Number _____

Date of Purchase _____

DEVICE DESCRIPTION

SYSTEM DESCRIPTION

The XPS® 3000 System consists of a power control console, footswitches, connection cables, and assorted handpieces to drive various burs, blades, drills, rasps, and cannulae.

XPS® 3000 CONSOLE — Provides power to the selected handpiece. In addition to the StraightShot® M4 Microdebrider and Visao™ High-Speed Otologic Drill, the system console also powers the StraightShot® Magnum® and Magnum® II handpiece, Powerforma® (High Speed Drill), Xcalibur® Hi-Torque and Hi-Speed Drills, and Skeeter® (microdrill) handpieces. It includes an integrated irrigation pump for irrigation of blades and burs and a second pump (optional) for motor coolant of the Visao™ High-Speed and Xcalibur® Hi-Speed Otologic Drills.

FOOTSWITCH — The Single Function footswitch controls speed; the Multifunction footswitch controls handpiece speed, rotation mode, and footswitch mode.

XPS® STRAIGHTSHOT® M4 MICRODEBRIDER — Features a finger wheel that allows the user to rotate the cutting tip of specially designed straight and curved rotatable blades. It is also compatible with non-rotating blades and burs. It includes a locking mechanism to prevent inadvertent rotation of non-rotating blades. The lightweight design combines high power and precision performance and can operate in forward mode of 12,000 rpm for bur operation and 5,000 rpm in oscillate for blade operation. The StraightShot® M4 also provides irrigation tubing management grooves to keep tubing out of the surgeon's way during a procedure.

STRAIGHTSHOT® MAGNUM® II MICRODEBRIDER HANDPIECE — Features a locking mechanism and allows adjustability of blade or bur tip alignment. The lightweight design combines high power and precision performance and can operate in forward mode of 12,000 rpm for bur operation and 5,000 rpm oscillate for blade operation.

STRAIGHTSHOT® MAGNUM® HANDPIECE — Features a locking mechanism and allows adjustability of blade or bur tip alignment. The lightweight design combines high power and precision performance.

VISAO™ HIGH-SPEED OTOLOGIC DRILL — The lightweight design is used in otologic bone drilling operations. It may be used with either standard burs or with Visao™ High-Speed Curved Burs.

XCALIBUR® HI-TORQUE AND HI-SPEED (WATER-COOLED) OTOLOGIC DRILLS — Has two motor assemblies, one hi-torque and one hi-speed (Water-Cooled); and one straight and one angled handpiece attachment. It is used in otologic bone drilling operations.

SKEETER® ULTRA-LITE OTO-TOOL — A slender, lightweight drill handpiece and burs specifically used in middle ear surgical procedures, including stapes footplate procedures. The Skeeter® may be powered from the XPS® 3000 console, XPS® 2000 console, or from a battery powered variable speed foot control.

POWERFORMA® OTOLOGIC DRILL — Straight and angled drill handpieces for otologic bone drilling. The Powerforma® connects, via an adapter plug, to the XPS® 3000 and XPS® 2000 consoles.

INDICATIONS

The XPS® 3000 is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery. An integral pump is provided for irrigation and a second integral pump may be provided for handpiece cooling.

Otology / neurotology indications include aural atresia, cholesteatoma, cochleostomy, development of a suture tunnel for cochlear implant fixation, drainage of petrous apex cyst from endaural and middle-fossa approach, endolymphatic hydrops, exostosis lesion removal, facial nerve decompression, mastoidectomy, mastoidotomy, ossicular chain reconstruction (OCR), otosclerosis, removal of ear tumors including acoustic neuroma, tympanoplasty and vestibular neurectomy.

Sinus indications include septoplasty, removal of septal spurs, polypectomy, antrostomy, ethmoidectomy/sphenoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR, transsphenoidal procedures, maxillary sinus polypectomy, circumferential maxillary antrostomy, choanal atresia, sphenoidectomy, and medial, lateral, and posterior frontal sinusotomy.

Nasopharyngeal/laryngeal indications include adenoidectomy, tracheal procedures, laryngeal polypectomy, laryngeal lesion debulking, including the surgical management of recurrent respiratory papillomatosis (RPP), and tonsillectomy, tonsillotomy for obstructive tonsillar disease and removal of endobronchial lesions.

Head and neck (ENT) indications include soft tissue shaving, rhinoplasty (narrowing of the bony vault and revision of the bony pyramid), removal and shaping of bone during rhinoplasty procedures, removal of adipose tissue (lipo debridement) in the maxillary and mandibular regions of the face, removal of acoustic neuroma, and incision and removal of soft tissue during plastic, reconstructive, and/or aesthetic surgery.

The XPS® 3000 system is indicated for use in orthopedic surgical procedures where the cutting and removal of soft and hard tissue or bone is required. These include spinal and small and large joint arthroscopic procedures.

CONTRAINDICATIONS

None are known.

PARTS LIST

Part #	Description
1897101	XPS® Model 3000 Console With Irrigation (one pump)
1897102	XPS® Model 3000 Console With Coolant and Irrigation (two pumps)
1898200T	XPS® StraightShot® M4 Microdebrider
1897200	StraightShot® Magnum® II Handpiece
1897200T	LandmarX® Magnum® II Handpiece
1897201	XPS® StraightShot® III Handpiece (Japan only)
1895400	XPS® Multifunction Footswitch
1895410	XPS® Single Function Footswitch
1895420	XPS® Multifunction Footswitch, Single Pedal
1895505	XPS® Accessory Cable, Short
1895820	Power Cord, North American, 115V
1895821	Power Cord, United Kingdom/Ireland, 240V
1895822	Power Cord, Continental Europe, 230V
1895823	Power Cord, Japan, 100V
1897821	Power Cord, 6 Meter, IEC320, 115V
3334800	Visao™ High-Speed Otologic Drill
3334800T	Visao™ High-Speed Otologic Drill, IGS Trackable
3333700	Xcalibur® Straight Hi-Torque Handpiece Attachment
3333705	Xcalibur® Straight Hi-Speed Handpiece Attachment
3333750	Xcalibur® Angled Hi-Torque Handpiece Attachment
3333755	Xcalibur® Angled Hi-Speed Handpiece Attachment
3333840	Xcalibur® Hi-Speed Motor Assembly, Water-Cooled
3333850	Xcalibur® Motor Assembly (Hi-Torque)
Accessories	
1895520	Powerforma® to XPS® Irrigator Tubing
1895522	StraightShot® to XPS® Irrigation Tubing, 5/Box
1896840	StraightShot® Magnum® Sterilization Tray
1897510	XPS® IV Pole Basket for Footswitch
1897851	XPS® Model 3000 System User's Guide
1897852	XPS® Model 3000 System Repair Manual
1898400	XPS® StraightShot® M4 Sterilization Tray
1994025	Adapter for Powerforma® Handpiece
3055601	Skeeter® Ultra-Lite Oto-Tool
3318501	Powerforma® Irrigation Tubing, Non-Sterile
3318502	Powerforma® Irrigation Tubing, Sterile, 5/bx
3318503	Irrigation Tubing Set, Sterile, 4/bx
3318506	Hi-Speed Drill Coolant Tubing Set, 2/bx
3318510	Handpiece Cable Cap, Small
3318515	Handpiece Cable Cap, Large
3318600	Clips for MPS®/Powerforma®/Xcalibur® Handpiece Cable/Tubing
3319001	MPS® Powerforma® Sterilization Tray
3319005	Case, Bur Rack, MPS®
3327700	MPS® Powerforma® Straight Handpiece
3327750	MPS® Powerforma® Angled Handpiece
3333610	Xcalibur® Irrigation Sleeve Assembly
3333620	Xcalibur® Hi-Torque Extended Bur Guard, Without Irrigation
3333625	Xcalibur® Hi-Speed Extended 75 mm Bur Guard, Without Irrigation
3333630	Xcalibur® Hi-Torque Extended Bur Guard, With Irrigation
3333635	Xcalibur® Hi-Speed Extended 75 mm Bur Guard, With Irrigation
3333645	Xcalibur® Hi-Speed Extended 64 mm Bur Guard, Without Irrigation
3333655	Xcalibur® Hi-Speed Extended 64 mm Bur Guard, With Irrigation
3333890	Xcalibur® Sterilization Tray
3333895	Xcalibur® Hi-Speed Drill Sterilization Tray
3334610	Visao™ Irrigation Sleeve
3334625	Visao™ Extended Bur Guard, Without Irrigation
3334635	Visao™ Extended Bur Guard, With Irrigation
3334895	Visao™ Sterilization Tray

For a complete list of system components and accessories
contact your local Medtronic Xomed representative
or call Customer Service at 1-800-874-5797 or 1-904-296-9600.

XPS® 3000 CONSOLE DESCRIPTION

FRONT CONSOLE

1. **SPEED DISPLAY** – When the system is running, the actual operating speed of the handpiece displays. When inactive, the display shows the top speed set by the operator.

2. **ROTATION INDICATOR** – Displays rotation mode (forward, reverse, or oscillate). Lights indicate selected rotation. Rotation may be selected at either the multi-function footswitch or with the center control button in the normal mode.

3. **PROCEDURE AND CURRENT OPERATIONS DISPLAY** – In operating mode, displays procedure-blade/bur setting and irrigation pump rate. In procedure selection/menu mode, it displays a choice of procedures, allowing the user to choose suggested operational settings for the current procedure.

4. **CONTROL BUTTON CLUSTER** – Operates in two modes, Normal and Procedure. In Normal operation, center button controls direction (forward and oscillate), top and bottom buttons control speed (increase and decrease), and left and right button control rate of irrigation (decrease and increase). Depressing the menu button activates the Procedure Mode. Arrow buttons control the cursor and the center button is the Select button. Operation of the speed and procedure functions is described below.

5. **HANDPIECE CONNECTORS** – Connect the appropriate handpiece to the console here. (Large connector for all handpieces except for Skeeter® handpiece.)

6. **FOOTSWITCH CONNECTOR** – Connect the footswitch to the console here. During standard operation the footswitch must be connected to operate the active handpiece.

7. **HANDPIECE IRRIGATION PUMP** – Pumps fluid through a tubing set to the blade or bur.

8. **XCALIBUR® HI-SPEED WATER COOLANT PUMP** – Pumps cooling fluid for the Water -Cooled drill motor assembly (available only on REF# 1897102).

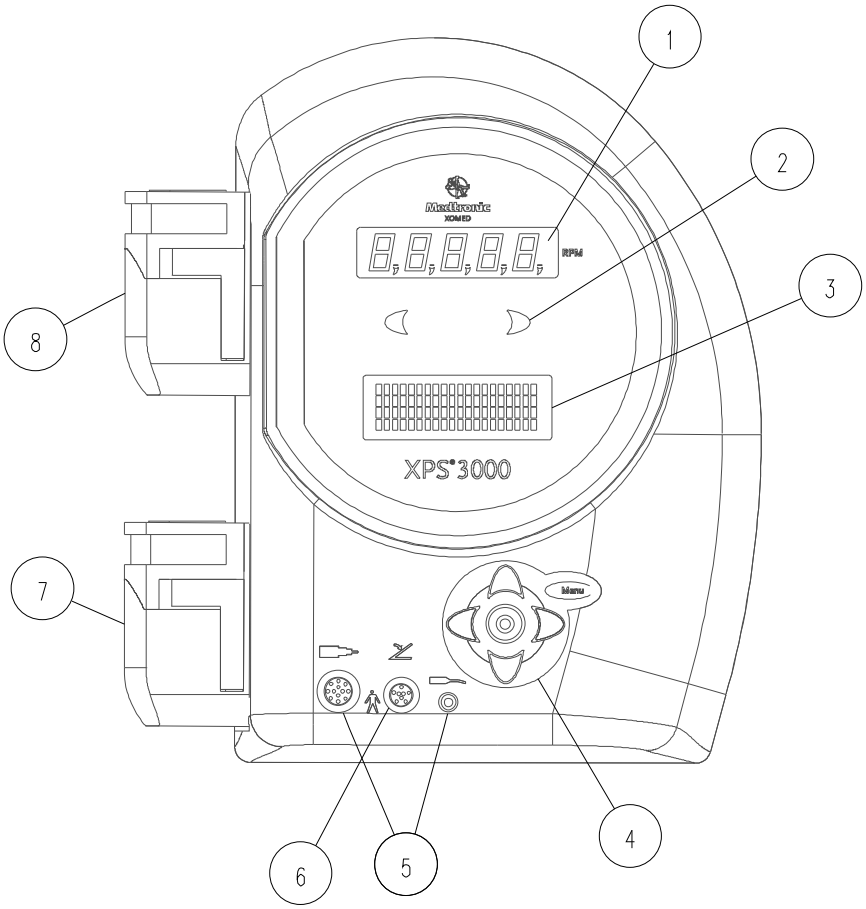


Figure 1 Front Console

REAR CONSOLE

1. **MANUAL START STOP BUTTON** – In the case of footswitch failure intraoperatively, button allows circulating nurse to manually turn handpiece operation on and off.

2. **ENDO-SCRUB® CABLE CONNECTOR** – Accepts accessory cable which powers the Endo-Scrub® 2.

3. **FUSE ACCESS** – REPLACE ONLY WITH 250V, 4.0A, Type F, 5 x 20mm fuses.

4. **POWER SWITCH** – Press the power switch to the "|" position to turn on the system. Press the switch to the "O" position to turn the system off.

5. **POWER CORD CONNECTOR** – Hospital grade power cord connects here.

6. **DB-9 CONNECTOR** – Connector for future data exchange.

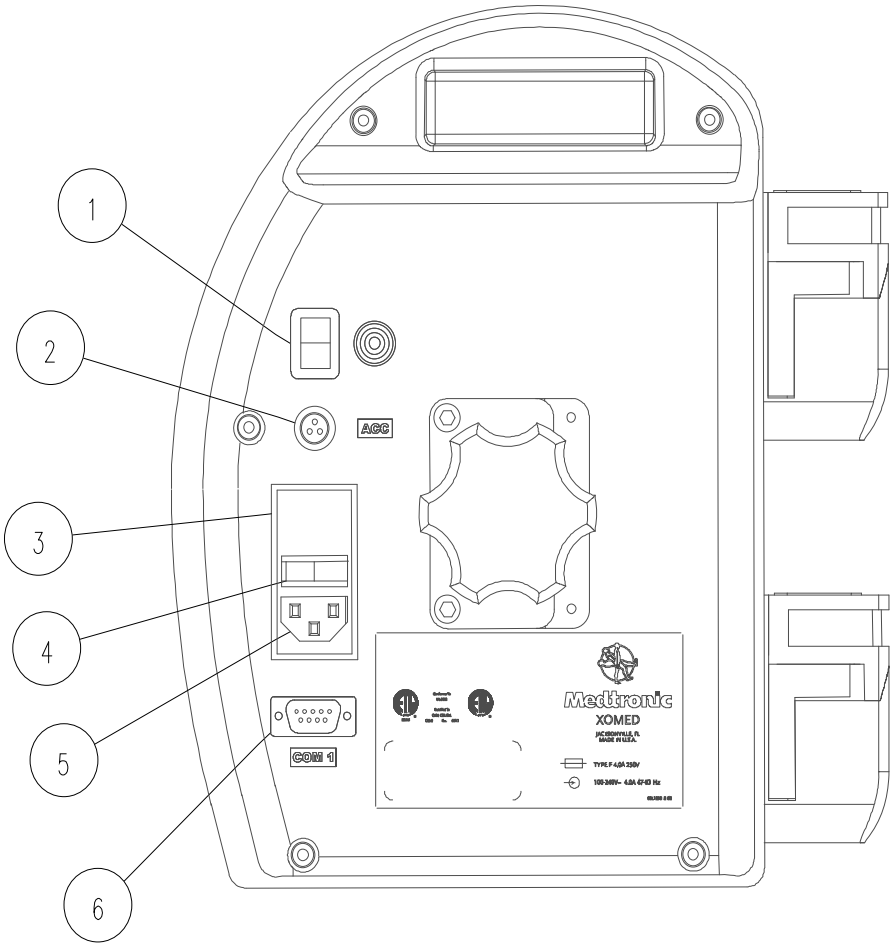


Figure 2 Rear Console

XPS® 3000 SET-UP AND USE

CAUTION

Inspect components for damage before use. Do not operate if components are damaged.

CABLE CONNECTIONS

To connect the cables to the console:

1. Insert the cable connectors by aligning the red dot on the cable connector with the red dot on the console connector.
2. Push connectors together. They should lock in place.

To disconnect the cables from the console:

1. Grasp the cable connector and gently pull back on the collar of the connector.
2. The connector will disconnect.

CAUTION

Grasp the cable connector; do not pull on the cable.

CONSOLE SET-UP

LANGUAGE SELECTION

The system is provided with a one pump console (1897101) or two pump console (1897102) defaulted to the customer's preferred language. Each console is capable of displaying six (6) languages as indicated below:

One Pump - 1897101	One Pump - 1897101	Two Pumps - 1897102	Two Pumps - 1897102
English	English	English	English
French	Spanish	French	Spanish
Italian	Danish	Italian	Danish
German	Finnish	German	Finnish
Spanish	Swedish	Spanish	Swedish
Dutch	Portuguese	Dutch	Portuguese

To change the language selection, simultaneously press the left and right arrow key on the control button cluster. Next, a menu will appear on the display showing the language choices. Use the arrow keys to move the cursor to the desired language and press the center key to select.

PRECAUTIONS

- System components should be operated and inspected for damage prior to use. **DO NOT USE SYSTEM IF DAMAGE IS APPARENT.**
- Do not allow the console to get wet. If liquid enters the console, damage could occur.

WARNING

- Only connect the console to hospital grade receptacles to ensure electrical grounding reliability.

1. Plug the power cord into the console and into the wall outlet.
2. Connect the handpiece (s) to the appropriate console connector (s).
3. Connect the footswitch cable to the console. See next section for instructions on footswitch operation.
4. Turn the console on by pressing the power switch on the back panel. The console will display default settings for the handpiece speed, direction of cutter rotation, and type of surgical procedure.
5. Figures 4 and 5 shows the default settings in Normal and Procedure Mode.

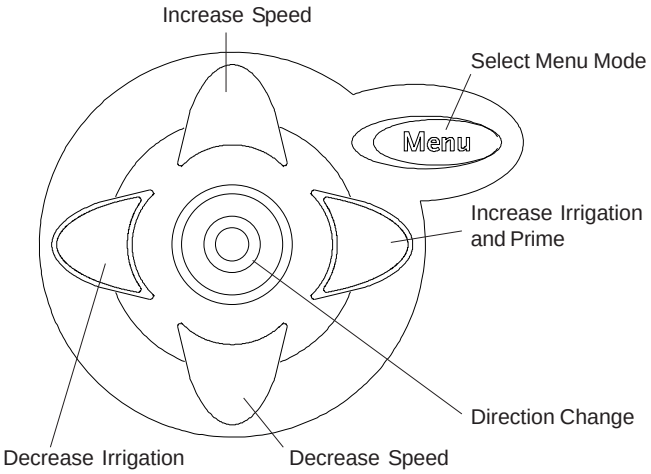


Figure 3-A Control Button Cluster-*Standard Mode*

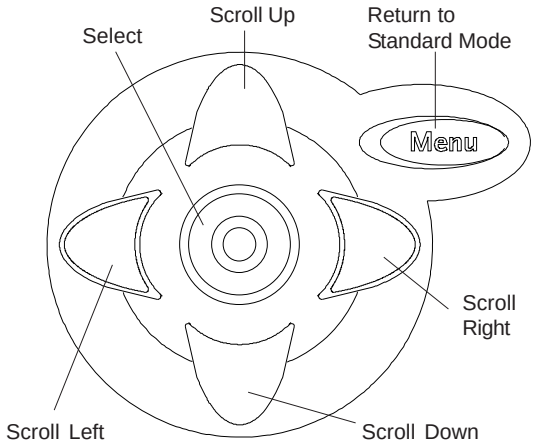


Figure 3-B Control Button Cluster-*Procedure Mode*

6. The control button cluster can control speed, direction, irrigation rate, and, in Procedure Mode (depress menu button), give the operator suggested operating speeds for different procedures.
7. Speeds may be adjusted by pressing top and bottom buttons to increase and decrease speed. Pump flow rate may be adjusted by pressing right (increase) and left (decrease) buttons; press and hold right button for prime. Direction (forward, reverse, oscillate) can be changed by pressing the center button.

Default speeds are listed below (* Not applicable).

HANDPIECE	OSCILLATE	FORWARD	REVERSE	DEFAULT MODE
StraightShot® M4	5,000 rpm	6,000 rpm	N/A*	OSCILLATE
Visao™ High-Speed Otologic Drill	N/A*	60,000 rpm	60,000 rpm	FWD
StraightShot® Magnum® II	5,000 rpm	6,000 rpm	N/A*	OSCILLATE
StraightShot® Magnum®	3,000 rpm	6,000 rpm	N/A*	OSCILLATE
Powerforma®	N/A*	43,000 rpm	43,000 rpm	FWD
Xcalibur® Hi-Torque Motor	N/A*	43,000 rpm	43,000 rpm	FWD
Skeeter®	N/A*	12,000 rpm	N/A*	FWD
Xcalibur® Hi-Speed Motor	N/A*	60,000 rpm	60,000 rpm	FWD

Handpiece operating ranges are listed below.

HANDPIECE	ROTATION MODE	LOW LIMIT	HIGH LIMIT
StraightShot® M4	FWD	500 rpm	12,000 rpm
StraightShot® M4	OSCILLATE	500 rpm	5,000 rpm
Visao™ High-Speed Otologic Drill	FWD or REV	10,000 rpm	80,000 rpm
StraightShot® Magnum® II	FWD	500 rpm	12,000 rpm
StraightShot® Magnum® II	OSCILLATE	500 rpm	5,000 rpm
StraightShot® Magnum®	FWD	300 rpm	6,000 rpm
StraightShot® Magnum®	OSCILLATE	300 rpm	3,000 rpm
Powerforma®	FWD or REV	10,000 rpm	52,000 rpm
Skeeter®	FWD	6,000 rpm	12,000 rpm
Xcalibur® Hi-Torque	FWD or REV	10,000 rpm	52,000 rpm
Xcalibur® Hi-Speed	FWD or REV	10,000 rpm	80,000 rpm

8. **ROTATION MODE** — Changed either by pressing the Rotation Control button (in the center of the control button cluster) on the console or, if the multifunction footswitch is used, depressing and releasing the left pedal.

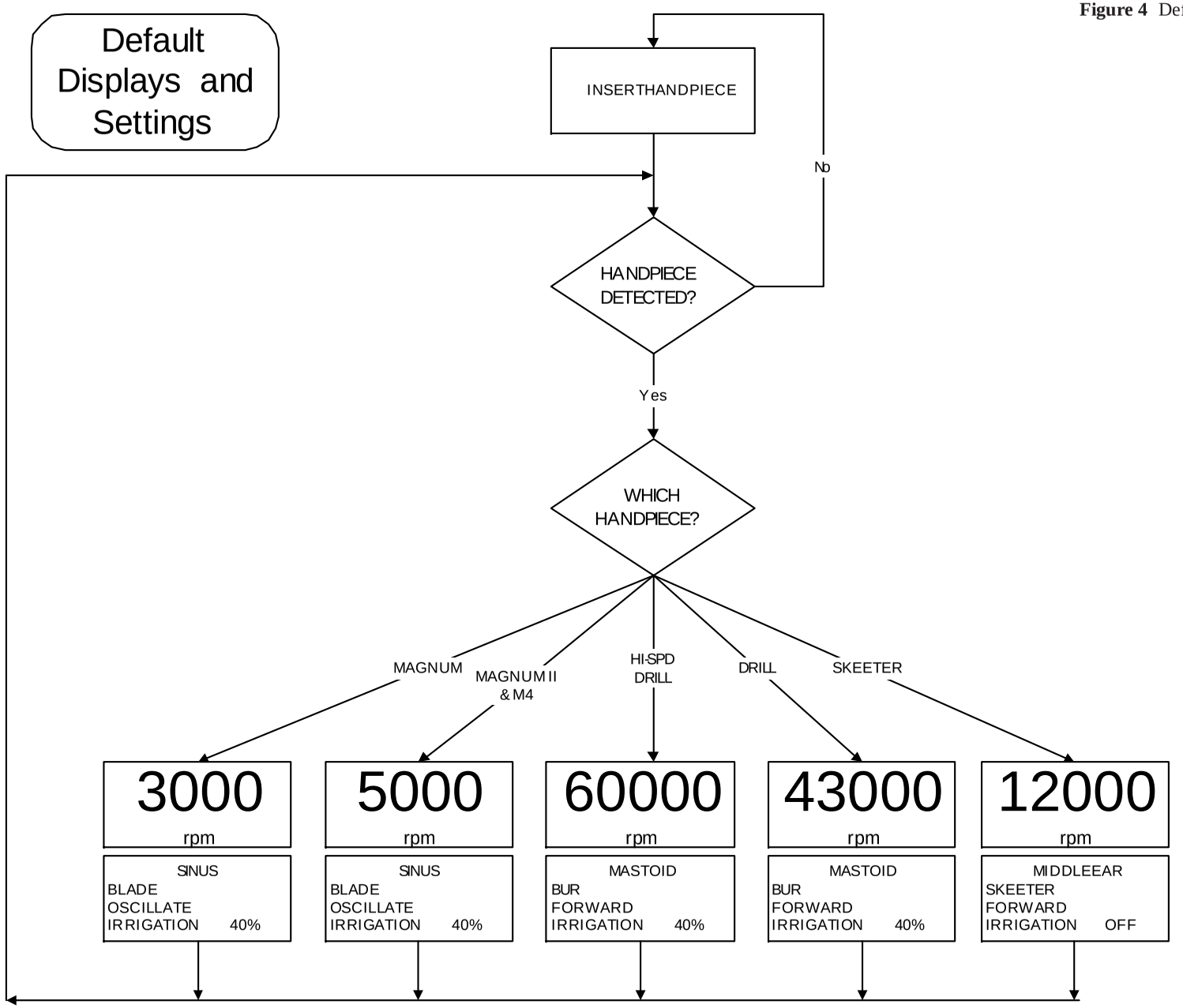
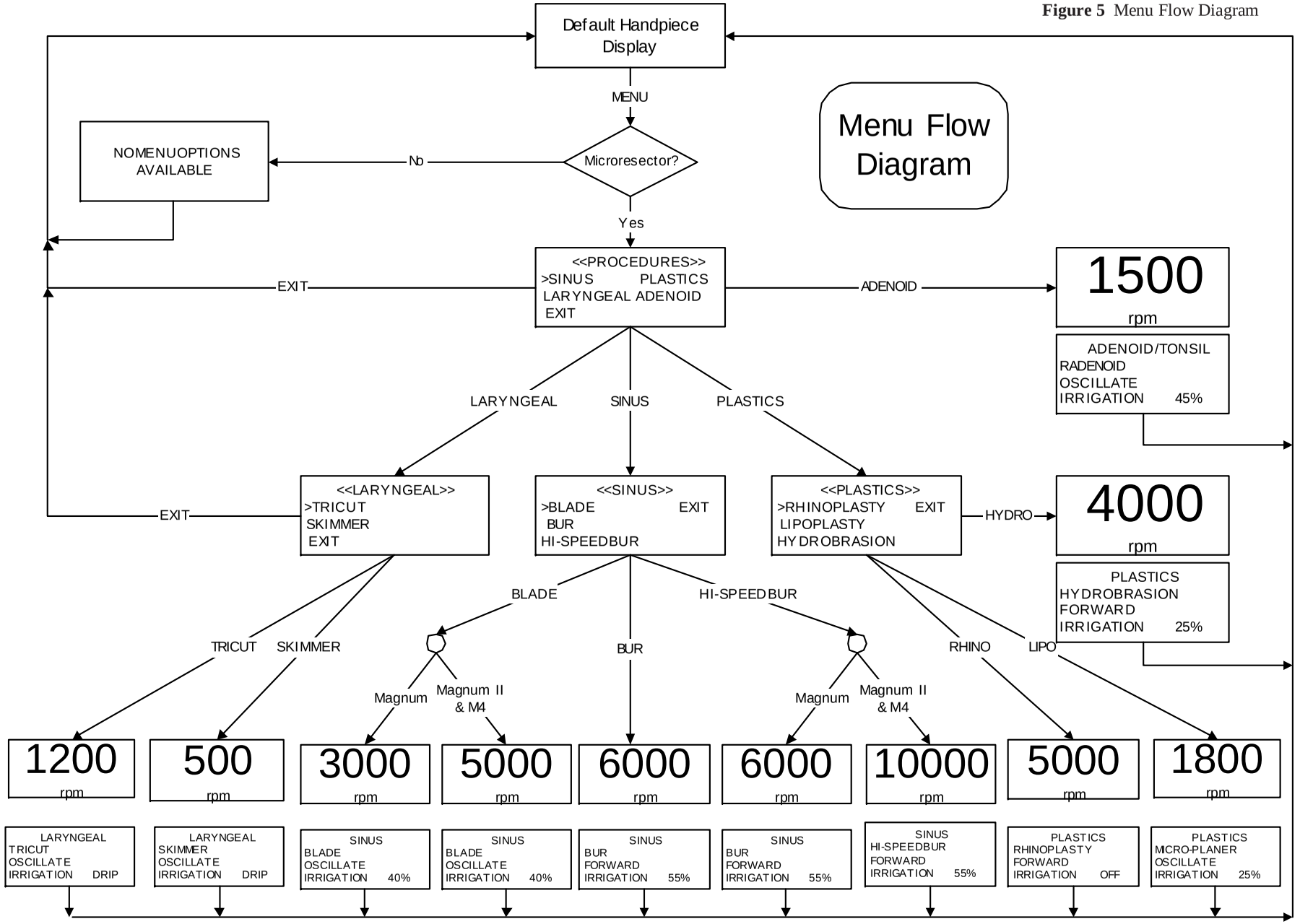


Figure 4 Default Displays and Settings

Figure 5 Menu Flow Diagram



XPS® MULTIFUNCTION FOOTSWITCH, 1895400

The multifunction footswitch allows control of handpiece speed, rotation mode, and footswitch mode. The footswitch cable connects with the console by a push connector.

1. **Right Pedal** — The right pedal provides control of handpiece speed. When in the VARIABLE operating mode, handpiece speed increases as the pedal is depressed. In the START/STOP operating mode, the handpiece automatically operates at the MAX SET SPEED displayed on the console when the pedal is depressed. The right pedal also activates the irrigation pump if connected.
2. **Left Pedal** — Depressing and releasing the left pedal changes the ROTATION direction (oscillate, forward, or reverse) of the handpiece. **Note:** Rotation mode may only be changed when the handpiece is not running.
3. **Top Button** — Depressing and releasing this button changes the FOOTSWITCH MODE (Variable or Start/Stop).

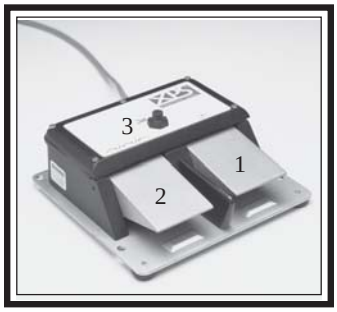


Figure 6-A
XPS® Multifunction Footswitch, 1895400

PRECAUTIONS

- **DO NOT** immerse the footswitch.
- **DO NOT** sterilize the footswitch.

XPS® MULTIFUNCTION FOOTSWITCH, SINGLE PEDAL, 1895420

The multifunction footswitch allows control of handpiece speed, rotation mode, and footswitch mode. The footswitch cable connects with the console by a push connector.

1. **Pedal** — The pedal provides control of handpiece speed. When in the VARIABLE operating mode, handpiece speed increases as the pedal is depressed. In the START/STOP operating mode, the handpiece automatically operates at the MAX SET SPEED displayed on the console when the pedal is depressed. The pedal also activates the irrigation pump if connected.
2. **Left Button** — Depressing and releasing this button changes the ROTATION direction (oscillate, forward, or reverse) of the handpiece. Note: Rotation mode may only be changed when the handpiece is not running.
3. **Right Button** — Depressing and releasing this button changes the FOOTSWITCH MODE (Variable or Start/Stop).

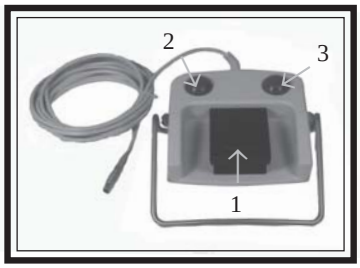


Figure 6-B
XPS® Multifunction Footswitch, Single Pedal, 1895420

PRECAUTIONS

- **DO NOT** immerse the footswitch.
- **DO NOT** sterilize the footswitch.

XPS® SINGLE FUNCTION FOOTSWITCH, 1895410

The single function footswitch operates only in a variable mode. It controls handpiece speed, which increases as the pedal is depressed. The pedal also activates the irrigation pump if connected. The footswitch cable connects with the console by a push connector.

Figure 7
XPS® Single Function Footswitch, 1895410

XPS® STRAIGHTSHOT® M4 AND MAGNUM® II MICRODEBRIDER SYSTEM SET-UP AND USE

The StraightShot® M4 and Magnum® II Microdebrider Drill Systems are intended for use with the XPS® Model 3000 Console, although they will operate with the XPS® 2000 Console. Likewise, the Straightshot® Magnum® will operate with the XPS® 3000 Console. The StraightShot® M4 and Magnum® II default at 5,000 rpm oscillate and 6,000 rpm forward. The StraightShot® Magnum® defaults at 3,000 rpm oscillate and 6,000 rpm forward. However, the StraightShot® M4 and Magnum® II have top operating speeds of 5,000 rpm oscillate and 12,000 rpm in forward while the StraightShot® Magnum® has top operating speeds of 3,000 rpm oscillate and 6,000 rpm in forward. If the StraightShot® M4 and Magnum® II are connected to the XPS® 2000 Console they will operate at the same speeds as the StraightShot® Magnum®. The multifunction or single function footswitches control the operating speeds of the handpiece.

The StraightShot® M4 and Magnum® II Microdebrider Systems support a number of Otorhinolaryngology indications listed under "Indications." Many disposable blades and burs are available for this purpose. Additionally, the XPS® 3000 console offers a procedure setting screen which recommends and defaults to suggested operating speeds for each procedure. The default settings can be adjusted. Speed can be adjusted, within allowable ranges, using the top and bottom buttons in the control button cluster. Direction (forward and oscillate) can be adjusted using the middle button. Pump flow rate for irrigation (bottom pump) is controlled with left and right buttons in the control button cluster.

Pressing the "menu" button accesses procedure menus. After pressing the menu button, top, bottom, right, and left buttons control the cursor on the display. The center button acts as the select button.

The StraightShot® M4 and Magnum® II Microdebrider Systems consist of the following main components:

- XPS® Model 3000 Console with integrated irrigation pump.
- StraightShot® M4 or Magnum® II Microdebrider Handpiece (to use the Image Guided capabilities of the Image Guided version of this handpiece, refer to the following User's Guides for your IGS system: LandmarX® ENT Image Guidance Systems, Treon® ENT Image Guidance System with LandmarX® Software, LandmarX Evolution® ENT Image Guidance System, LandmarX Evolution® Plus ENT Image Guidance System, LandmarX® Element System and iNav™ Element System).
- Footswitch
- XPS® Microdebrider blades and burs.

BEFORE SURGERY

WARNINGS

- Refer to "Warnings Before Surgery" in the front section of this manual.

The following instructions are recommended for set-up and use of the StraightShot® M4 and Magnum® II Microdebrider Systems with the XPS® Model 3000 Console.

1. Inspect components for damage and determine if system is ready to use.
2. On IV pole, mount XPS® Model 3000 console and plug unit into power source.
3. Connect gray accessory cable (REF # 1895505) between Endo-Scrub® 2 and XPS® Model 3000 console if Endo-Scrub® 2 is being used.
4. On the rear of the console, turn the power switch to the ON position.
5. With tubing set (REF # 1895522) purchased separately or included with straight XPS® blades, spike the irrigation bag, then place and secure tubing set into the lower pump in console (top pump is intended for cooling discussed in drill set-up section).
6. Transferring sterilized StraightShot® M4 or Magnum® II handpiece plug/cord from scrub to circulator, plug StraightShot® M4 or Magnum® II into the large handpiece port on the XPS® 3000 console.

7. Connect footswitch into the XPS® Model 3000 and place under operating table.
8. Place desired XPS® blade or bur in the StraightShot® M4 or Magnum® II collet mechanism as described in the next section.
9. Attach standard suction tubing to exhaust port of StraightShot® M4 or Magnum® II and to dedicated suction canister.
10. Clip irrigation tubing, suction tubing, and handpiece cable together with clips enclosed with XPS® blade tubing set, or with StraightShot® M4. Clips are permanently attached to electrical cable.
11. To prime the irrigation tubing, press and hold the right ► arrow key. The pump will run in Prime mode until the right ► arrow key is released.
12. After pump has been primed, set irrigation pump rate to desired setting.
13. If handpiece speed other than default is desired, increase and decrease with top and bottom buttons. **DO NOT** use burs above the speed indicated on the bur label.
14. If direction other than oscillate is desired, change between forward and oscillate by using the center button.
15. If suggested procedure settings are desired, press menu button, use top, bottom, left, and right buttons to scroll through the menu to pick procedure and blade. Press center button to select an option. See menu flow diagram, Figure 5.

The following set-up is recommended for the StraightShot® M4 and Magnum® II Microdebrider System:

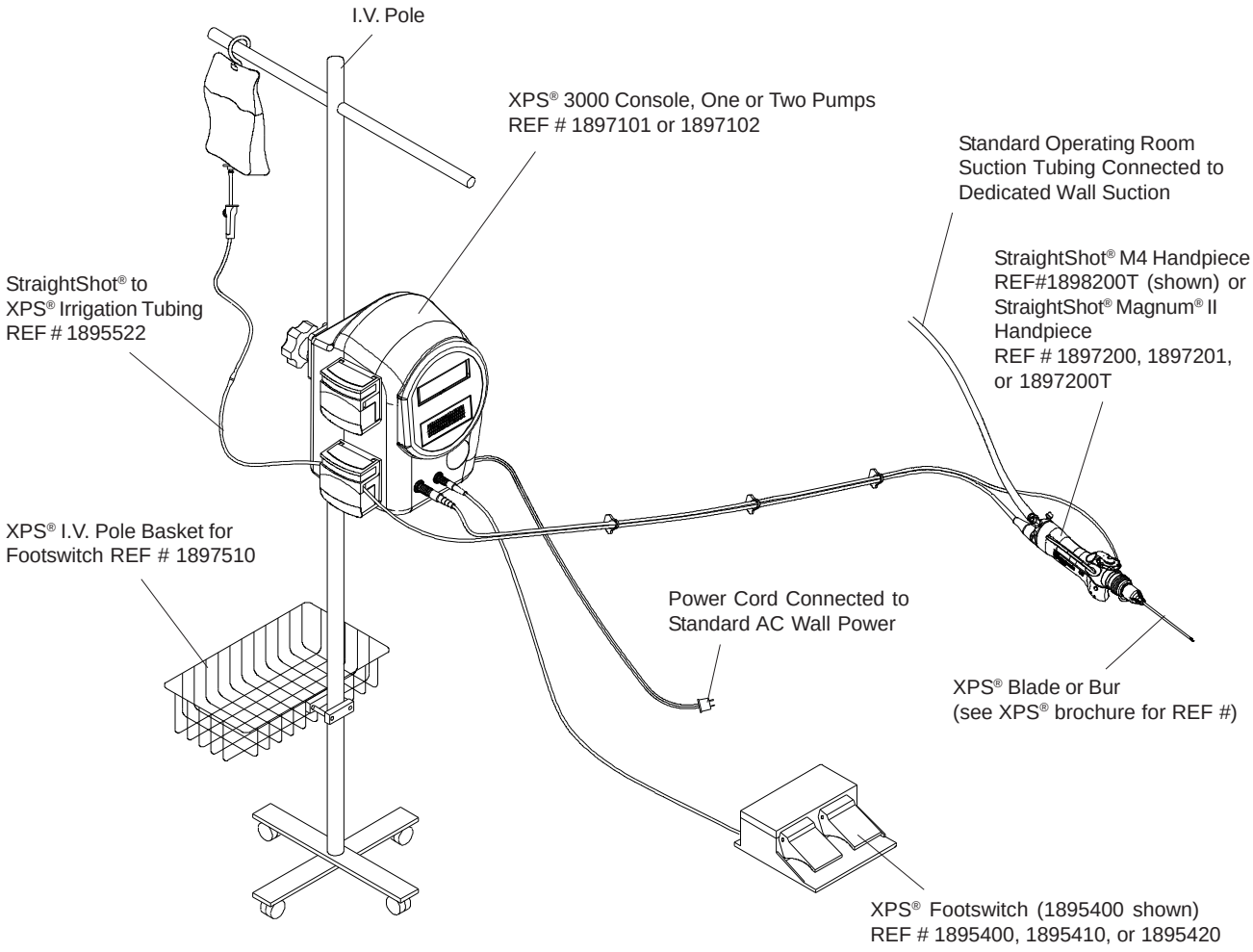


Figure 8 XPS® StraightShot® M4 and Magnum® II Microdebrider System

XPS® STRAIGHTSHOT® M4 AND MAGNUM® II HANDPIECE ACCESSORIES

WARNINGS

- Use adequate irrigation from a separate user-provided irrigating source. The use of a bur without irrigation may cause an inordinate amount of heat buildup resulting in thermal injury to tissue.
- Disposable devices are for single-use only. Do not attempt to sterilize disposable devices. The disposables are packed sterile and not intended for repeat use. To prevent contamination use only once.
- Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using XPS® accessories. The use of powered reciprocating/rotating instruments may result in vibration-related injury. Use appropriate precautions.
- Employ visualization when using rotating XPS® accessories. Discontinue powered application in the event of lack of visualization of the surgical site.
- Use methods at the operative site to control bleeding that do not compromise patient safety during at-risk surgery.
- Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is replaced. Damaged parts may deposit metal shavings on surgical site.
- Do not use any parts other than Medtronic Xomed, Inc. system components as damage or substandard performance could result.
- Remove and discard accessories following local regulations for proper disposal of contaminated materials.
- Do not modify accessories used with the handpiece. Performance could be diminished with modified accessories.
- Insertion of metal objects in blade or bur tip may cause the blade or bur to break leaving fragments in the wound. The fragments may be difficult to remove, causing irritation, inflammation and foreign-body response at surgical site.
- Always keep the cutting tip of the accessory away from fingers and loose clothing. Prevent laceration of user and cross-contamination through compromised glove.
- Do not change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
- Discontinue use of curved bur if tip begins to wobble and replace bur to prevent unintended tissue removal from patient.
- Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination.
- Bending or prying may break the accessory, causing harm to patient or staff.
- Accessories are available for resection of soft tissue and bone for surgical procedures. Use of accessories depends on the intended application and patient needs. Sharp-cutting powered accessories induce bleeding and removal of significant tissue and bone.
- Insertion of metal objects in blade tip may cause the blade to break leaving fragments in the wound. The fragments may be difficult to remove, causing irritation, inflammation and foreign-body response at surgical site.
- Use lock on StraightShot® M4 handpiece to prevent inadvertant rotation of blade or bur during use.
- When precise location of the blade tip is required, engage the rotation lock on the handpiece, then calibrate and verify the blade tip on the Image Guided Surgery (IGS) system. Always lock the StraightShot® M4 handpiece when driving non-rotatable blades to maintain their IGS calibration.

BLADE OR BUR INSTALLATION

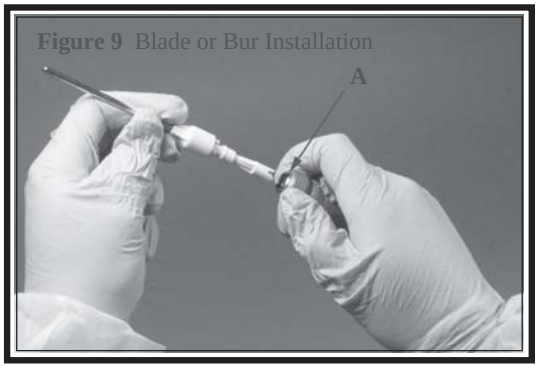


Figure 9 Blade or Bur Installation

1. Using thumb, depress the locking collar (A) on the front of the handpiece.
2. Insert blade or bur with a slight rotating motion until blade or bur is seated. For rotatable straight blades, orient the irrigation barb at the 3 o'clock position for right-handed surgeons and 9 o'clock for left-handed surgeons. For rotatable curved blades, orient the irrigation barb at 3 o'clock. To fully seat an M4 rotatable blade, adjust the finger wheel with small back-and-forth motions.
3. Align blade or bur tip opening to desired position.
4. Release the locking collar.
5. Pull on the blade or bur to ensure engagement and visually check to make sure distal tip of inner blade is in contact with the distal tip of the outer cannula.
6. For non-rotating blades, orient the blade or bur to desired position (usually 12 o'clock for the cutting surface and 6 o'clock for the irrigation barb) and locking mechanism (D).

TUBING ATTACHMENT

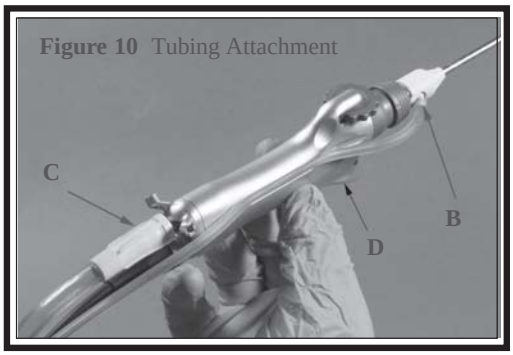


Figure 10 Tubing Attachment

1. Adjust the clamp on the irrigation tubing to the off position and spike the bag of irrigant.
2. Push the free end of the irrigation tubing onto the irrigation port on the blade (B) until tubing passes barb on the port and is secure.
3. Attach suction tubing securely to the suction port on the handpiece (C).
4. Secure the suction and irrigation tubing to the handpiece cable with the clip (if provided) and the white clamps included in the blade packaging.

XPS® STRAIGHTSHOT® M4 AND MAGNUM® II SURGICAL PRECAUTIONS

- XPS® Blades should be operated in the oscillate mode only. Operating in the forward mode may cause damage to the blade. XPS® burs should be operated in the forward mode only.
- Be sure the blade is fully engaged in the Microdebrider and verify the tip is fully engaged with the outer cannula prior to use.
- To prevent damage to curved blades, disconnect suction tube prior to changing blade or bur during procedure.
- The StraightShot® Magnum® II and StraightShot® M4 Microdebriders are intended to operate at speeds greater than 6,000 rpm ONLY when used with the XPS® High Speed bur line.

Table. Using Wheel and Lock on StraighShot® M4 Handpiece linked to an Image Guided Surgery (IGS) System.

	Location of tip must be known during procedure.	Variation preferred during procedure.	
		Tip Location	Blade-window
Non-Rotatable Blades, Including Laryngeal	1. Adjust blade tip to desired location. 2. Activate LOCK. 3. Mount IGS attachement to handpiece using Allen wrench. 4. Calibrate blade tip on IGS. 5. Wheel is not usable.	1. Do not LOCK handpiece. 2. Do not refer to IGS for indication of location. 3. Wheel is usable to vary tip location.	Not applicable.
M4 Rotatable Blades	1. Adjust blade tip to desired location. 2. Mount IGS attachment to handpiece using Allen wrench. 3. Calibrate blade tip on IGS.	1. Release blade from collet. 2. Rotate blade into one of four present orientations. 3. Lock blade into collet.	1. Do not LOCK handpiece. 2. Mount IGS attachment ot handpiece using Allen wrench. 3. Calibrate blade tip on IGS. 4. Wheel is usable to vary window location.

AFTER SURGERY

BLADE OR BUR REMOVAL

1. If the irrigation pump is not used, turn off the irrigation flow using the roller clamp on the irrigation tubing.
2. Remove and discard the tubing following local regulations for proper disposal of contaminated materials.
3. Depress the locking collar of the handpiece and pull the blade or bur out of the handpiece and discard following local regulations for proper disposal of contaminated materials.

VISAO™ AND XCALIBUR® DRILL SYSTEM SET-UP AND USE

The Visao™ and Xcalibur® Hi-Speed Drills are used with the XPS® Model 3000 console with two integral pumps (one for handpiece cooling, the other for irrigation). The Xcalibur® Hi-Torque Drill System is intended for use with the XPS® Model 3000 Console, or the XPS® Model 2000 console and the optional XPS® Irrigator Pump, for the controlled dissection and removal of bone during ENT surgery.
Speed of the XPS® 3000 Drill System is set by use of the top and bottom buttons on the control button cluster on the console, and controlled by using the XPS® single function or multifunction footswitch. Rate of Irrigation is controlled by left and right (decrease and increase) buttons on the control button cluster.
The Visao™ High-Speed Otologic Drill operates with Medtronic Xomed straight burs and Visao™ High Speed Curved Burs to meet the needs of the surgeon, eliminating the need for handpiece attachments.
The Xcalibur® drills have the ability to operate on the XPS® Model 3000 with interchangeable Hi-Speed water-cooled and Hi-Torque motors and straight or angled handpieces to meet the needs of the surgeon. Note that only the Xcalibur® Hi-Speed Straight or Xcalibur® Angled Handpieces will fit onto the Xcalibur® Hi-Speed (Water-Cooled) Motor Assembly.

The Visao™ and Xcalibur® Drill's bur notch mechanism incorporates Medtronic Xomed surgical burs of diameter .092 inches (2.34mm) that are at least 1.73 inches (44mm) long.

The XPS® 3000 Drill System is comprised of the following main components:

- XPS Model 3000 Console with Optional Coolant Pump
- Footswitch
- Either: Visao™ High-Speed Otologic Drill
- Or: Xcalibur Hi-Speed and Hi-Torque Electric Motors,
  Xcalibur Hi-Speed and Hi-Torque, Straight or Angled Handpiece Attachments.

The following set-up is recommended for the Hi-Torque Motor:

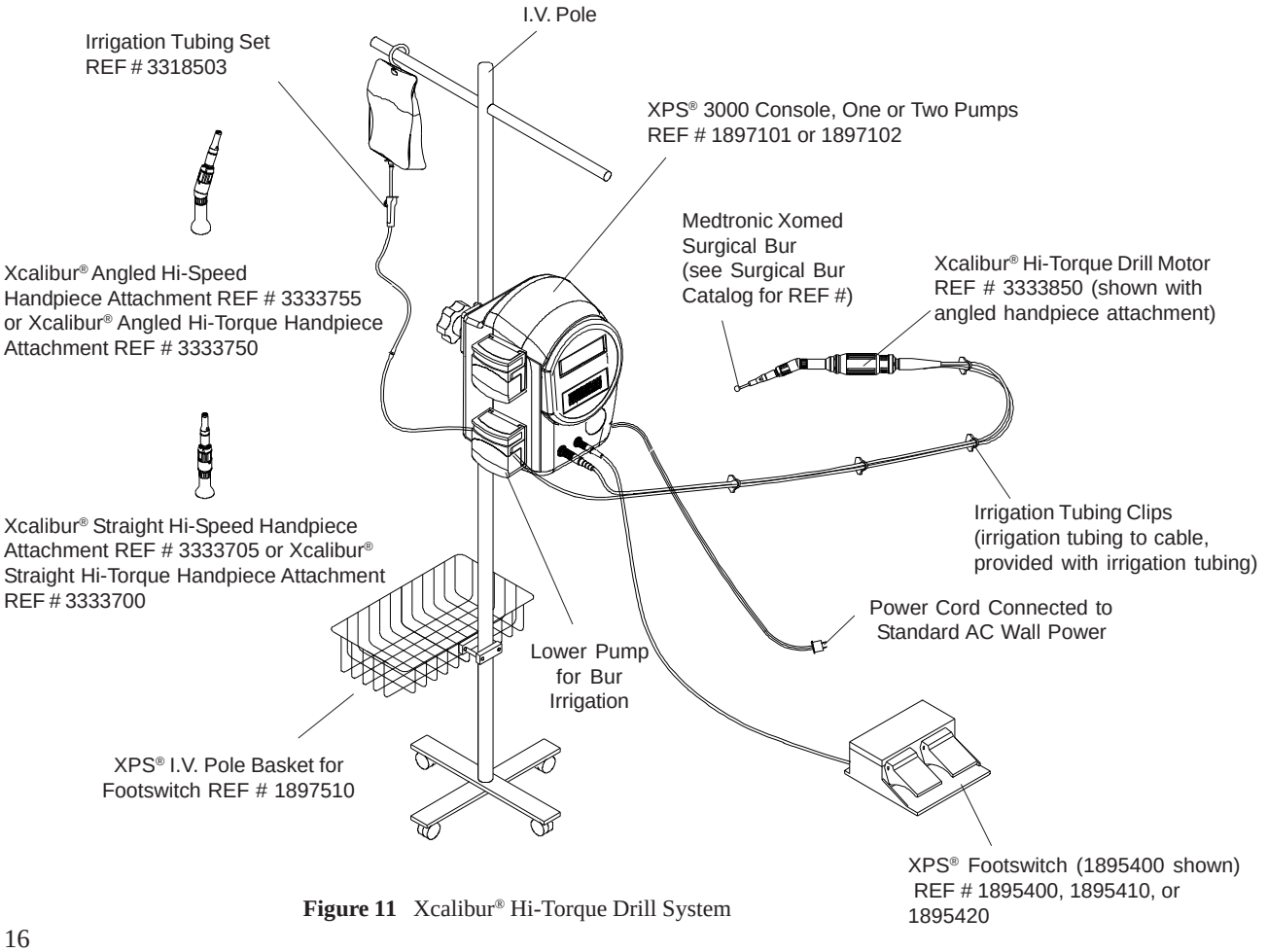


Figure 11 Xcalibur® Hi-Torque Drill System

The following set-up is recommended for the Visao™ High Speed Otologic Drill (Water-Cooled) and Xcalibur® Hi-Speed (Water-Cooled) Motor:

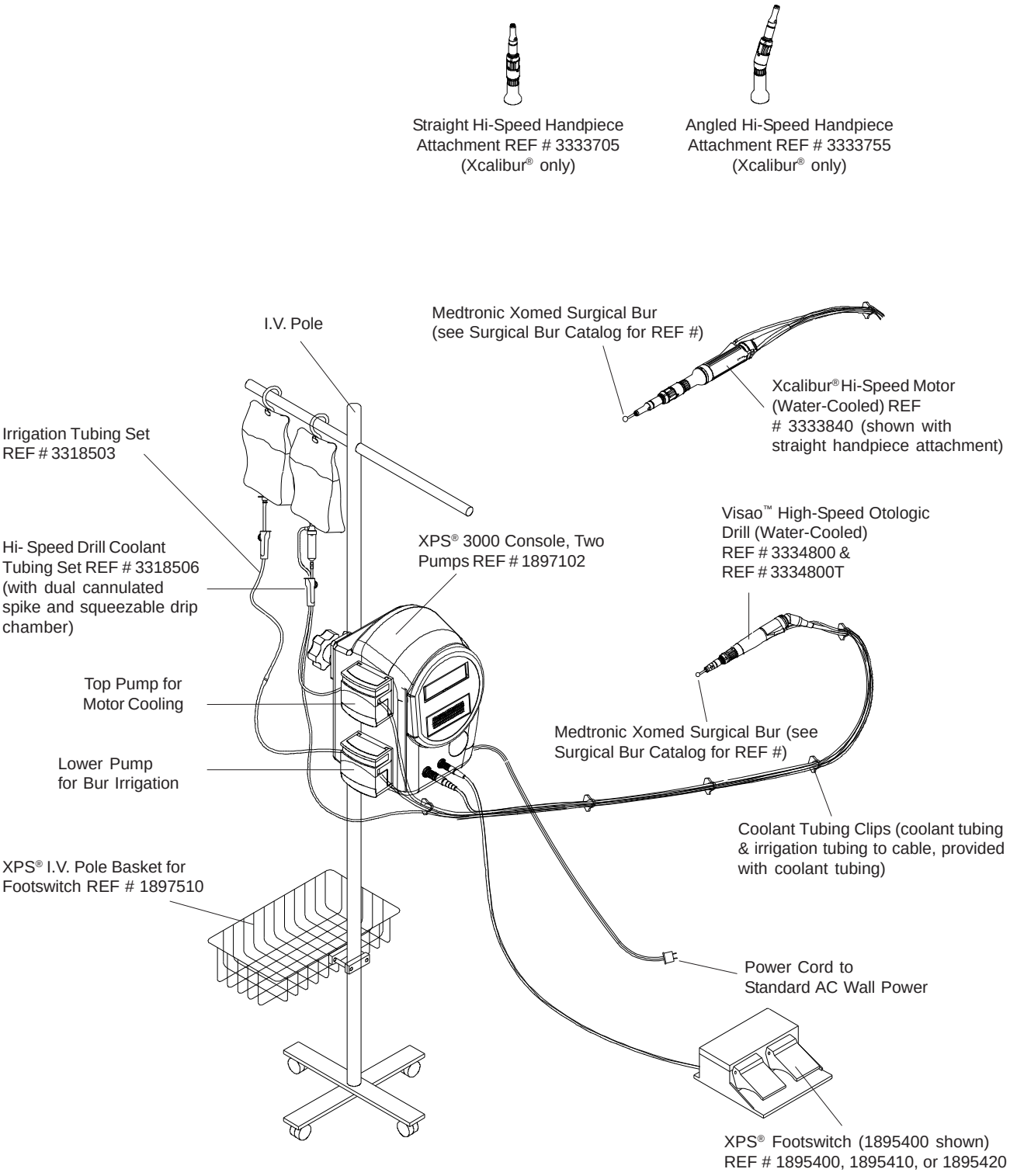

Straight Hi-Speed Handpiece Attachment REF # 3333705 (Xcalibur® only)
Angled Hi-Speed Handpiece Attachment REF # 3333755 (Xcalibur® only)
I.V. Pole
Medtronic Xomed Surgical Bur (see Surgical Bur Catalog for REF #)
Xcalibur® Hi-Speed Motor (Water-Cooled) REF # 3333840 (shown with straight handpiece attachment)
Irrigation Tubing Set REF # 3318503
Hi- Speed Drill Coolant Tubing Set REF # 3318506 (with dual cannulated spike and squeezable drip chamber)
XPS® 3000 Console, Two Pumps REF # 1897102
Visao™ High-Speed Otologic Drill (Water-Cooled) REF # 3334800 & REF # 3334800T
Top Pump for Motor Cooling
Lower Pump for Bur Irrigation
Medtronic Xomed Surgical Bur (see Surgical Bur Catalog for REF #)
Coolant Tubing Clips (coolant tubing & irrigation tubing to cable, provided with coolant tubing)
XPS® I.V. Pole Basket for Footswitch REF # 1897510
Power Cord to Standard AC Wall Power
XPS® Footswitch (1895400 shown) REF # 1895400, 1895410, or 1895420

Figure 12 Visao™ High-Speed Otologic Drill or Xcalibur® Hi-Speed Drill System

BEFORE SURGERY

WARNINGS

- Refer to “Warnings Before Surgery” in the front section of this manual.

The following instructions are recommended for set-up and use of the Visao™ High-Speed Otologic Drill, Xcalibur® Hi-Speed (Water-Cooled) Drill system and/or the Xcalibur® Hi-Torque Drill System with the XPS® Model 3000:

1. Inspect components for damage and determine if system is ready to use.
2. On IV pole, mount XPS® Model 3000 console and plug unit into power source.
3. On the rear of the console, turn the power switch to the ON position.
4. Plug the connector end of the motor cord into the XPS® Model 3000 console.
5. Connect footswitch into XPS® Model 3000 console and place under operating table.
6. If irrigation is desired, connect Irrigation Tubing (REF # 3318503) to irrigation port on Visao™ Irrigation Sleeve (REF # 3334610) or, Visao™ Extended Bur Guard with Irrigation (REF # 3334635) or, Xcalibur® Irrigation Sleeve (REF # 3333610) or, Xcalibur® Hi-Speed Extended 75 mm Bur Guard with Irrigation (REF # 3333635) or, Xcalibur® Hi-Speed Extended 64 mm Bur Guard with Irrigation (REF # 3333655) or, Xcalibur® Hi-Torque Extended Bur Guard with Irrigation (REF # 3333630). Spike irrigation bag and place the short piece of silicone tubing through the lower pump. Close pump head.
7. If the Visao™ High-Speed Otologic Drill (REF # 3334800 or REF # 3334800T) or Xcalibur® Hi-Speed, Water-Cooled, Motor Assembly (REF # 3333840) is used, attach each of the tubes from the Coolant Tubing (REF # 3318506) to the ports on the handpiece. Spike a second large bag of irrigation fluid (sterile water, or saline if sterile water is not available). Place the short piece of silicone tubing through the coolant pump (top pump on the XPS® Model 3000 console).
8. Clip Irrigation Tubing to Visao™ motor cable clips or Xcalibur® motor cable using clips provided with tubing set.
9. If the Visao™ Drill is used, both the irrigation tubing and coolant tubing can be retained in the clips on the handpiee cable. If the Hi-speed (Water-Cooled) motor is used, clip Hi-Speed Coolant Tubing and Irrigation Tubing (if used) to Xcalibur® Motor Cable using clips provided with the tubing set. (The clips in the Irrigation Tubing will not be needed.)
10. To prime the irrigation tubing, press and hold the right ► arrow key. The pump will run in Prime mode until the right ► arrow key is released. This function runs simultaneously with the coolant pump.
11. To prime the coolant pump, press and hold the right ► arrow key. The pump will run in Prime mode until the right ► arrow key is released. This function runs simultaneously with the irrigation pump. Alternatively, ensure the handpiece bur lock is closed (align small dots on handpiece), then depress the foot pedal momentarily (1-2 seconds). After the foot pedal is released, the cooling pump will continue to run for approximately one minute. Continue to prime the cooling system until all bubbles are removed.
12. Select drill speed settings by depressing the top or bottom buttons (increase and decrease speed) in the control button cluster.
13. Unlock the Visao™ or Xcalibur® Drill handpiece collet by rotating lock ring 1/4 turn, insert desired bur (rotating to engage the base of the bur completely into position in the handpiece), then rotate the lock ring 1/4 turn back to lock the bur into the handpiece (aligning the small dots on the handpiece).
14. Always tug bur for security. Repeat step 13 if necessary.
15. **IMPORTANT:** Test drill by depressing foot pedal prior to use. The system is now ready to use. Note that the cooling pump will continue to run for about one (1) minute after your foot is removed from the foot pedal.

VISAO™ AND XCALIBUR® BUR INSTALLATION AND TUBING ATTACHMENT

WARNINGS

- Do not change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
- Do not use burs above the speed indicated on the bur label. Exceeding speed may cause the burs to break.
- Carefully inspect burs prior to and following each use for excessive wear, fragmentation, eccentricities or other defects. Do not use dull, damanged or bent burs. Use of dull burs can reduce the handpiece effectiveness and cause the handpiece temperature to increase.
- Do not attempt to resharpen used burs. Worn burs should be replaced with new ones frequently to ensure effective cutting and control of the drill.
- Excessive pressure applied to bur may cause bur fracture. Should a bur fracture during use, extreme care must be exercised to ensure that all fragments of the bur are retrieved and removed from the patient. Unremoved bur fragments may cause tissue damage to the patient.
- Test for bur wobble (eccentricity) at desired speed prior to use. Use a bur guard (Xcalibur® only) if needed. Select a new bur or reduce speed if wobble is observed.
- Test for bur wobble (eccentricity) at the desired speed prior to use. Select a new bur or reduce speed if wobble is observed. Eccentricity of the bur can cause bur vibration and may result in excessive tissue and bone destruction and hearing damage. Always examine the operation of each bur in the handpiece before each use. Operating certain burs at high speed can cause vibration of the bur.

Visao™ High-Speed Curved Burs Only

- Keep the cooling sleeve irrigated to prevent thermal injury to tissue.
- During procedures near nerves, keep bur and bur cannula away from tissue to minimize the potential for thermal injury.
- For procedures near nerves, nerve monitoring should be used to alert the user of the potential for injury.

BUR ATTACHMENT

1. Using thumb and index finger, twist handpiece locking mechanism counter clockwise to unlock handpiece.
2. Insert desired Medtronic Xomed Surgical Bur into handpiece, giving bur a 1/4 turn as it is seated (or until it seats fully into the handpiece).
3. Lock and secure bur by twisting handpiece locking mechanism clockwise.
4. Tug on bur to ensure bur is secured and locked into the handpiece.

CURVED BUR INSTALLATION (VISAO™ HIGH SPEED CURVED BURS ONLY)

1. Using thumb and index finger, twist the handpiece locking collar to the unlocked position.
2. Insert the curved bur onto the nose of the handpiece loosely and rotate the curved bur to the desired angular position.
3. Firmly push the curved bur hub onto the handpiece until it snaps in place. Gently twist the curved bur hub back and forth to ensure it is completely seated in the angular detents.
4. Using thumb and index finger, twist the handpiece locking collar to the locked position.
5. Push the bur head into the handpiece until it snaps in place.
6. Gently tug on the bur head to ensure it is locked in place.

TUBING ATTACHMENT - IRRIGATION

1. During initial set-up, ensure drill irrigation tubing is clipped into place along the motor electrical cable using clips provided with tubing set.
2. Insert tubing from the Visao™ or Xcalibur® Drill handpiece on to the Visao™ Irrigation Sleeve (REF # 3334610) or, the Visao™ Extended Bur Guard with Irrigation (REF # 3334635) or, Xcalibur® Irrigation Sleeve Assembly (REF # 3333610) or, Xcalibur® Hi-Speed Extended 75 mm Bur Guard with Irrigation (REF # 3333635) or, Xcalibur® Hi-Speed Extended 64 mm Bur Guard with Irrigation (REF # 3333655) or, Xcalibur® Hi-Torque Extended Bur Guard with Irrigation (REF # 3333630).
3. Rotate the irrigation sleeve to the desired surgeon position.
4. Spike the irrigation bag.
5. Install the tubing into the pump.
6. Prime the tubing set.
7. Test tubing flow and set-up by depressing footswitch.

TUBING ATTACHMENT - COOLING (WATER-COOLED MOTOR)

1. During initial set-up, ensure water-cooled drill coolant tubing is clipped into place along the motor electrical cable. For Xcalibur®, use clips provided with tubing set. (The irrigation tubing, if used, can be attached using these same clips, and the clips in the irrigation tubing set will not be needed.)
2. Connect tubing set to the cooling ports of the water-cooled motor.
3. Spike a large bag of irrigation fluid (preferably sterile water, but saline may be used).
4. Place the short section of silicone tubing through the cooling pump (upper pump).
5. Prime the cooling tubing set while squeezing drip chamber a few times. Continue to prime until air bubbles no longer occur at the coolant bag. **IMPORTANT:** Ensure all air is purged out of the motor. Roll the motor back and forth during priming to encourage air out of the motor's cooling jacket.

VISAO™ AND XCALIBUR® SURGICAL PRECAUTIONS

- Always ensure that the bur is securely engaged into the handpiece prior to operating the system.
- When operating or testing the Poweforma®, Xcalibur® and Visao™ drill handpieces, ensure the bur is properly inserted and locked into the handpiece. Running the drill with the collet unlocked can damage the locking mechanism.
- Improper priming of the Xcalibur® and Visao™ High-Speed Drills will result in excessive handpiece temperature.
- The Visao™ and Xcalibur® Hi-Speed Water-Cooled Drills work only with the XPS® 3000. Use without water-bag will damage the motor in the handpiece.
- **IMPORTANT:** Always examine operation of each bur in a handpiece before each use. Operating certain burs at high speeds can cause vibration of the bur. The following are suggestions for reducing bur vibration:

  > Reduce handpiece operating speed.
  > Use only burs that are rated for High Speed operation.
  > Use Visao™ Extended Bur Guards (REF # 3334625 or 3334635) with 64 mm or 75 mm burs in the Visao™ High-Speed Otologic Drill.
  > Use Xcalibur® Hi-Speed Extended 64 mm Bur Guards (REF # 3333645 or 3333655) with 64 mm burs in the Xcalibur® Hi-Speed Drill.
  > Use Xcalibur® Hi-Speed Extended 75 mm Bur Guards (REF # 3333625 or 3333635) with 75 mm burs in the Xcalibur® Hi-Speed Drill.
  > Use Xcalibur® Hi-Torque Extended Bur Guards (REF # 3333620 or 3333630) with 75 mm burs in the Xcalibur® Hi-Torque Drill.
  > Operate handpiece at 50% speed when using burs 75 mm or longer.
  > Select a new bur.

POWERFORMA® DRILL SYSTEM SET-UP AND USE

The Powerforma® Drill System is intended for use with the XPS® Model 3000 console, or the XPS® Model 2000 console and optional XPS® Irrigator Pump, for the controlled dissection and removal of bone during ENT surgery. The primary application of the Powerforma® Drill System is mastoid bone drilling. Speed of the Powerforma® Drill System is set by use of the top and bottom buttons on the control button cluster on the console, and controlled by using the XPS® single function or multifunction footswitch. Rate of Irrigation is controlled by left and right (decrease and increase) buttons on control button cluster.

The Powerforma® Drill System's bur notch mechanism incorporates Medtronic Xomed surgical burs of diameter .092 inches (2.34 mm) that are at least 1.73 inches (44 mm) long.

The Powerforma® Drill System is comprised of the following main components:

- XPS® Model 3000 Console
- Straight or Angled Handpiece
- Footswitch
- Adapter for Powerforma® Handpiece

The following set-up is recommended for the Powerforma® Drill System:

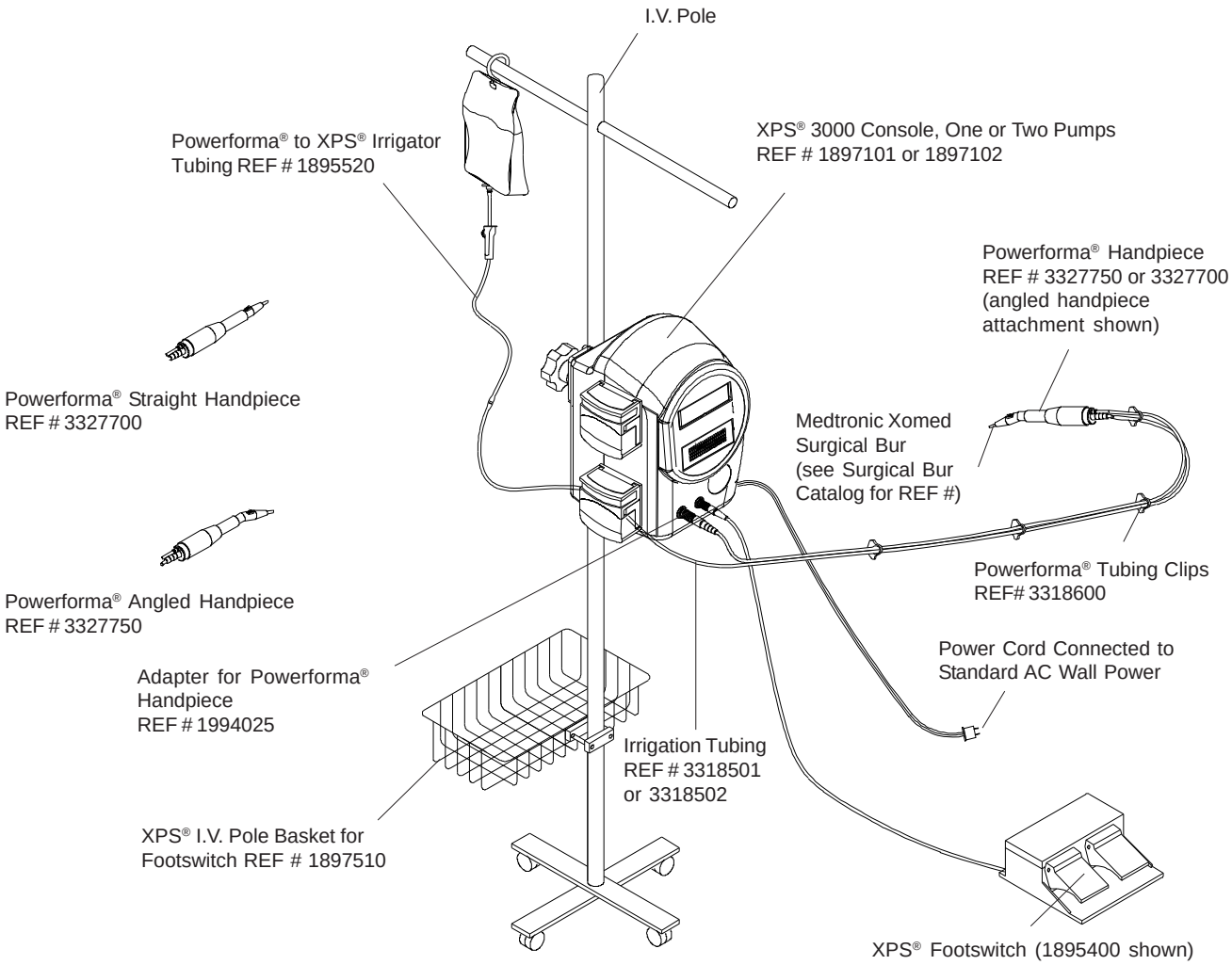

I.V. Pole
Powerforma® to XPS® Irrigator Tubing REF # 1895520
XPS® 3000 Console, One or Two Pumps REF # 1897101 or 1897102
Powerforma® Handpiece REF # 3327750 or 3327700 (angled handpiece attachment shown)
Powerforma® Straight Handpiece REF # 3327700
Medtronic Xomed Surgical Bur (see Surgical Bur Catalog for REF #)
Powerforma® Angled Handpiece REF # 3327750
Powerforma® Tubing Clips REF# 3318600
Power Cord Connected to Standard AC Wall Power
Adapter for Powerforma® Handpiece REF # 1994025
Irrigation Tubing REF # 3318501 or 3318502
XPS® I.V. Pole Basket for Footswitch REF # 1897510
XPS® Footswitch (1895400 shown) REF # 1895400, 1895410, or 1895420

Figure 13 Powerforma® Drill System

BEFORE SURGERY

WARNINGS

- Refer to “Warnings Before Surgery” in the front section of this manual.

The following instructions are recommended for set-up and use of the Powerforma® Drill System with XPS® Model 3000:

1. Inspect components for damage and determine if system is ready to use.
2. On IV pole, mount XPS® Model 3000 console and plug unit into power source.
3. On the rear of the console, turn the power switch to the ON position.
4. Attach the XPS® to Powerforma® Tubing (REF # 1895520) to the Powerforma® Irrigation Tubing (REF # 3318501) which should already be attached to the Powerforma® Handpiece.
5. Clip the Powerforma® Irrigation Tubing (REF # 3318501) along the handpiece electrical cord with Powerforma® Tubing Clips (REF # 3318600).
6. Transfer the connector end of the handpiece electrical cable, along with the irrigation tubing, to the circulating nurse. Be careful to maintain sterility.
7. Spike the irrigation bag and place the XPS® to Powerforma® Tubing (REF # 1895520) through the lower pump. Close the pump head.
8. Connect footswitch into XPS® Model 3000 console and place under operating table.
9. To prime the irrigation tubing, press and hold the right ▶ arrow key. The pump will run in Prime mode until the right ▶ arrow key is released.
10. After tubing has been primed, set irrigation pump rate to desired setting.
11. Select drill speed settings by depressing the top or bottom buttons (increase and decrease speed) in the control button cluster.
12. To insert a bur, pull back on the bur release button with your thumb, and slide the bur shaft into the handpiece chuck. Twist the bur a quarter-turn (1/4) or until it slides fully into place. Allow the bur release button to slide forward, which locks the bur into place.
13. Always tug bur to ensure it is securely locked in place. Repeat step 12 if necessary.
14. Test drill by depressing foot pedal. The system is now ready to use.
15. To remove the bur, pull back on the bur release button, and pull the bur out of the chuck.

POWERFORMA® BUR INSTALLATION AND TUBING ATTACHMENT

WARNINGS

- Ensure bur is properly secured in the Powerforma® handpiece prior to surgeon activation.
- **DO NOT** change burs with handpiece running.
- Use adequate irrigation. The use of a bur without irrigation may cause an inordinate amount of heat build-up resulting in thermal injury to tissue.
- Test for bur wobble (eccentricity) at desired speed prior to use. Select a new bur or reduce speed if wobble is observed.
- Excessive pressure applied to bur may cause bur fracture which may cause injury.
- **DO NOT** use dull, damaged, or bent burs. Change burs frequently for optimal performance. Use of dull burs can reduce handpiece cutting effectiveness and cause handpiece temperature to increase.

BUR ATTACHMENT

1. Using your thumb, pull back on the bur release button.
2. Insert desired Medtronic Xomed surgical bur into handpiece, giving bur a 1/4 turn as it is seated (or until it seats fully into the handpiece).
3. Allow the bur release button to slide forward.
4. Tug on bur to ensure bur is secured and locked into the handpiece.

TUBING ATTACHMENT - IRRIGATION

1. During initial set-up, ensure drill irrigation tubing is clipped into place on drill using clips provided with tubing set.
2. Connect tubing set from the Powerforma® Drill handpiece into XPS® Powerforma® tubing set (REF # 1895520).
3. Install XPS® to Powerforma® tubing set (REF # 1895520) into the lower pump. Close the pump head.
4. Prime the tubing set.
5. Test tubing flow and set-up by depressing footswitch.

POWERFORMA® SURGICAL PRECAUTIONS

- Excessive noise from the bur when drilling close to the cochlea or ossicular chain may cause hearing damage.
- Excessive force may lead to bur bending, breakage or excess vibration. If the bur fractures during use, the resultant sharp surfaces may cause lacerations of the body tissue. A bur which fractures inside a patient may also cause tissue injury and necessitate emergency procedures for extraction.
- Eccentricity of the bur can cause bur vibration and may result in excess tissue and bone destruction and hearing damage.
- When operating or testing the Powerforma® drill handpiece, ensure bur is properly inserted into the handpiece. Running the handpiece with an unsecured bur can cause damage. Running a handpiece without a bur is not recommended.
- During procedures, operating room technicians and nurses should always check bur function, fit, tightness, and security in the handpiece before handing off to surgeon for use.
- Always examine operation of each bur in a handpiece before each use. Operating certain burs at high speeds can cause vibration of the bur. The following are suggestions for reducing bur vibration:

  > Reduce handpiece operating speed.
  > Operate handpiece at 50% speed when using burs 75 mm or longer.
  > Select a new bur.

SKEETER® ULTRA-LITE OTO-TOOL SYSTEM SET-UP AND USE

The Skeeter® Ultra-Lite Oto-Tool System is a slender, lightweight drill handpiece with burs, specifically used in middle ear surgical procedures, including stapes footplate surgery. The Skeeter® handpiece and burs may be used with the XPS® Model 3000 via direct connection with the Skeeter® handpiece connector. The lightweight Skeeter® Ultra-Lite Oto-Tool Handpiece weighs 57 grams. The drill shaft diameter is approximately 2mm and is angled approximately 15 degrees from the plane of the handpiece. The shaft angulation and small diameter maximize visualization of the surgical field during drill use.

The Skeeter® Ultra-lite Oto-Tool Handpiece can be powered by three (3) 9 volt batteries housed in the Accelerator Foot Control. However, when used with the XPS® Model 3000 console, the handpiece plugs directly into the console and is operated using the XPS® single function or multifunction footswitch. The footswitch allows variable speed operation of the handpieces ranging from very slow to high speed in excess of 12,000 rpm.

The Skeeter® is used with the Oto-Flex bur. The Oto-Flex bur designed for use with the Skeeter® are composed of a flexible stainless steel shaft with a bur and a PTFE bearing at one end and the handpiece engagement at the other. The inside of the PTFE bearing is lightly coated with silicone spray to reduce operating friction.

COLOR CODING

For ease of identification of size, all Oto-Flex Burs are color coded. Diamond Burs are further differentiated from Carbide Burs by a white band on the shaft of each Diamond Bur. A Color Code Chart is conveniently provided in the base of the Oto-Tool System Sterilization Case. The bur size identification color code is as follows:

Violet:	0.5mm	Yellow:	0.8mm	Brown:	1.8mm
Blue:	0.6mm	Orange:	1.0mm	Red:	2.3mm
Green:	0.7mm	Gray:	1.4mm	Black:	Specialty

For a complete listing of Skeeter Ultra-Lite Oto-Tool System, consult the “System Component and Accessories” section of the Skeeter User’s Guide (68E1279).

The Skeeter® Ultra-Lite Oto-Tool System consists of the following main components:

- XPS® Model 3000 Console
- Skeeter® Ultra-Lite Oto-Tool Handpiece
- Footswitch
- Oto-Flex burs

The following set-up is recommended for the Skeeter® Ultra-Lite Oto-Tool System:

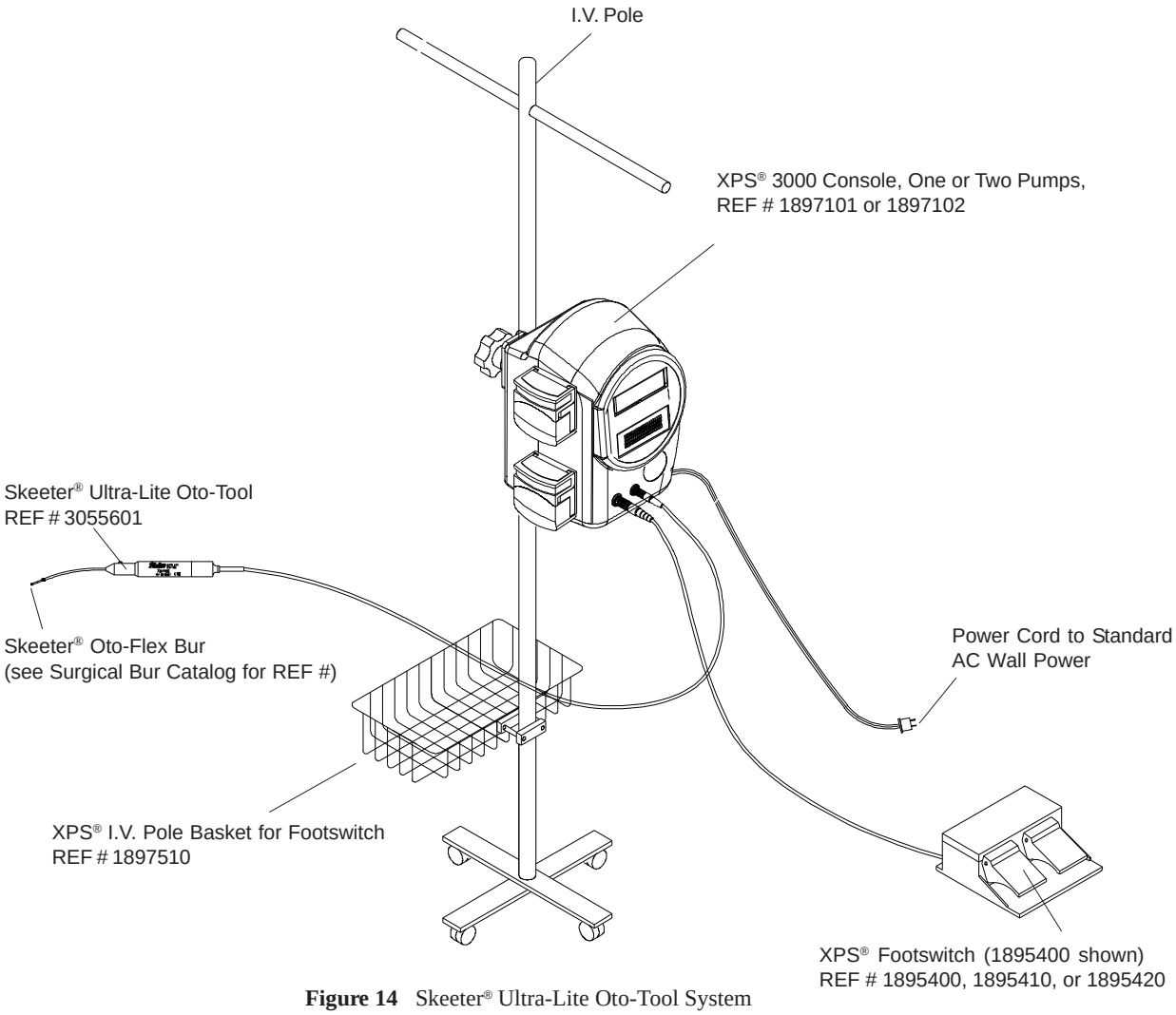

I.V. Pole
XPS® 3000 Console, One or Two Pumps,
REF # 1897101 or 1897102
Skeeter® Ultra-Lite Oto-Tool
REF # 3055601
Skeeter® Oto-Flex Bur
(see Surgical Bur Catalog for REF #)
Power Cord to Standard
AC Wall Power
XPS® I.V. Pole Basket for Footswitch
REF # 1897510
XPS® Footswitch (1895400 shown)
REF # 1895400, 1895410, or 1895420

Figure 14 Skeeter® Ultra-Lite Oto-Tool System

BEFORE SURGERY

WARNINGS

- Refer to "Warnings Before Surgery" in the front section of this manual.
- **DO NOT** attempt to resharpen used burs. Worn burs should be replaced with new ones frequently to ensure effective cutting and control of the drill.
- Carefully inspect burs both prior to and following each use for signs of excessive wear, fragmentation, eccentricities or other defects. Replace any suspicious bur with a new one prior to use.
- Should a bur fracture in use, extreme care must be exercised to ensure that all fragments of the bur are retrieved and removed from the patient. Unremoved bur fragments may cause tissue damage to the patient.

PRECAUTIONS

- Always handle handpieces with care to avoid damage.
- Make certain the appropriate bur is securely fastened into the handpiece prior to use. USE ONLY MEDTRONIC XOMED ROTARY BURS INTENDED FOR USE WITH THE SKEETER® ULTRA-LITE OTO-TOOL.
- Excessive noise from the bur when drilling close to the cochlea or ossicular chain may cause hearing damage.
- Excessive force may lead to bur bending, breakage or excess vibration. If the bur fractures during use, the resultant sharp surfaces may cause lacerations of the body tissue. A bur which fractures inside a patient may also cause tissue injury and necessitate emergency procedures for extraction.
- Eccentricity of the bur can cause bur vibration and may result in excess tissue and bone destruction and hearing damage.
- **DO NOT** attempt to bend needle nose or effect repairs to the system.

The following instructions are recommended set-up and use of the Skeeter® Ultra-Lite Oto-Tool with the XPS® 3000:

1. Inspect components for damage and determine if system is ready to use.
2. On IV pole, mount XPS® Model 3000 console and plug unit into power source.
3. On the rear of the console, turn the power switch to the ON position.
4. After removal of the handpiece from the sterilization tray, transfer the connector from the sterile field to the circulating nurse.
5. The cable is plugged into the appropriate (smallest) connector in the console.
6. Connect footswitch into XPS® Model 3000 console and place under operating table.
7. Load the desired bur for the procedure into the handpiece by inserting the bur shaft through the distal end of the handpiece with a slight twisting motion while simultaneously depressing the bur release button. The bur is locked into place when a "click" is noted. Locking of the bur should be checked prior to use by firmly pulling on the bur after the "click" is noted. To remove the bur from the handpiece, depress the Bur Release Button on the handpiece and carefully pull the bur out.
8. Select drill speed settings by depressing the top and bottom buttons (increase and decrease speed) in the control button cluster.
9. Tug the bur to ensure its security in the handpiece.
10. Test drill by depressing foot pedal. The system is now ready to use.

CLEANING AND STERILIZATION GUIDELINES

The following cycles are compatible with the each handpiece as listed below; however, **it is the responsibility of each health care facility to validate the sterilization process with their particular equipment and procedures to assure sterility.**

PRECAUTION

- **DO NOT** cold soak sterilize the handpiece in glutaraldehyde. This will void the Warranty.

WARNINGS

- Disconnect power before cleaning the unit.
- Inspect components for any damage before and after each use. If you see damage, do not use the system until it is repaired.
- After cleaning and sterilization, verify functionality by operating the equipment prior to the surgical procedure.

AFTER SURGERY

XPS® 3000 Console

- **DO NOT** immerse the console.
- Turn the power off and unplug console before cleaning.

Footswitches

- **DO NOT** immerse the footswitch.

XPS® StraightShot® M4, StraightShot® Magnum® II and StraightShot® Magnum® Handpieces

- **DO NOT** immerse the handpieces.
- Remove and discard the tubing and blade/bur following local regulations for proper disposal of contaminated materials.

Visao™ High-Speed Otologic Drill

- **DO NOT** immerse the handpiece.
- Remove bur from handpiece prior to cleaning.

Xcalibur® Hi-Torque Handpiece

- **DO NOT** immerse the handpiece attachments or the motor assembly.
- Remove bur from handpiece prior to cleaning.
- **DO NOT** insert cleaning plug in the front of the motor assembly before sterilization.
- **DO** insert cleaning plug in the front of the motor assembly before cleaning.

Xcalibur® Hi-Speed Handpiece

- **DO NOT** immerse the handpiece attachments or the motor assembly.
- Remove bur from handpiece prior to cleaning.
- **DO NOT** insert cleaning plug in the front of the motor assembly before sterilization.
- **DO** insert cleaning plug in the front of the motor assembly before cleaning.

Powerforma® Handpiece

- Remove bur from handpiece prior to cleaning.
- **DO NOT** immerse the handpiece.

Skeeter® Handpiece

- Remove bur from handpiece prior to cleaning.
- **DO NOT** immerse the handpiece.

Oto-Flex Burs

- **DO NOT** immerse the burs.

AFTER SURGERY (continued)

XPS Disposable Blades and Burs

- If the irrigation pump is not used, turn off the irrigation flow using the roller clamp on the irrigation tubing.
- Remove and discard the tubing following local regulations for proper disposal of contaminated materials.
- Depress the locking collar of the handpiece and pull the blade or bur out of the handpiece and discard following local regulations for proper disposal of contaminated materials.

Medtronic Xomed Reusable Burs for Mastoid Drilling

- Initiate cleaning immediately after surgery (see cleaning section).

CLEANING

The following cycles are compatible with the each handpiece as listed below; however, **it is the responsibility of each health care facility to validate the sterilization process with their particular equipment and procedures to assure sterility.**

PRECAUTIONS

- **DO NOT** use organic solvents such as acetone or isopropyl alcohol to clean the bur chuck.
- USE ONLY an enzymatic detergent and distilled water for cleaning after every case or as required.
- **DO NOT** clean the handpieces in an ultrasonic cleaner or allow them to be fully immersed in any soaking solution. These procedures may result in damaging the handpieces beyond repair.

XPS ®3000 Console

- Wipe down the console with standard disinfectant.
- Dry the console with a clean, non-abrasive cloth. Wipe dry before storing.
- Be sure to dry off the console after cleaning. Moisture inside the console could cause damage.

Footswitches

- **DO NOT** immerse the footswitch.
- Clean the outside of the footswitch by wiping with standard disinfectant.

XPS® StraightShot® M4, StraightShot® Magnum® II and StraightShot® Magnum® Handpieces

- **DO NOT** immerse the handpiece.
- Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth.
- Gently clean the handpiece with a moistened soft bristle brush or pipe cleaner, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit.
- Hold the handpiece with the front end pointed downward during rinsing.
- Dry the handpiece and cable with a lint-free towel. Make sure to dry off the electrical connection on the cable ends.
- Apply a small amount of silicone spray into front-end collet and outside of handpiece. Wipe dry before storing.
- **Sterilize the handpieces immediately after cleaning.**

Visao™ High-Speed Otologic Drill, Irrigation Sleeves, and Bur Guards

- **DO NOT** immerse the handpiece.
- After surgery, clean the irrigation sleeves and bur guards with an enzymatic detergent solution. Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth.
- A chuck brush cleaner (REF# 3112500) or an appropriately sized small (plastic bristle) bore brush may be inserted into the distal end of the Visao™ handpiece, irrigation sleeves and bur guards to assist in removing fluids, tissue, or bone fragments.
- Rinse out the distal end of the handpiece. Shake excess water from the handpiece.
- Ensure all water is drained from the cooling housing. If saline was used for cooling during surgery, use distilled water to rinse the housing prior to draining.
- Using distilled water, rinse saline from the irrigation nozzles. Drain the nozzle of all water.
- **Sterilize the handpiece, irrigation sleeves, and bur guards immediately after cleaning.**

CLEANING (continued)

Xcalibur® Hi-Torque and Hi-Speed Straight and Angled Handpiece Attachments, Irrigation Sleeves, and Bur Guards

- **DO NOT** immerse the straight and angled handpiece attachments.
- After surgery, clean the irrigation sleeves and bur guards with an enzymatic detergent solution. Wipe the straight and angled handpiece attachments with disinfectant applied to a clean non-abrasive cloth.
- A chuck brush cleaner (REF# 3112500) or an appropriately sized small (plastic bristle) bore brush may be inserted into the distal end of the Xcalibur® handpiece attachments, irrigation sleeves and bur guards to assist in removing fluids, tissue, or bone fragments.
- Rinse out the distal end of the handpiece. Shake excess water from the handpiece attachments.
- Using distilled water, rinse saline from the irrigation nozzles. Drain the nozzle of all water.
- **Sterilize the handpiece, irrigation sleeves, and bur guards immediately after cleaning.**

Xcalibur® Hi-Torque Motor

- **DO NOT** immerse the motor assembly.
- Ensure that the cleaning plug is inserted into the front of the motor assembly.
- After surgery, wipe down motor cables and motor housing with disinfectant.
- If using a dishwasher, place handpiece in a vertical position (motor up) to allow water drainage.
- **Sterilize the motor assembly immediately after cleaning.**

Xcalibur® Hi-Speed Motor

- **DO NOT** immerse the motor assembly.
- Ensure that the cleaning plug is inserted into the front of the motor assembly.
- After surgery, wipe down motor cables and motor housing with disinfectant.
- Ensure all water is drained from the motors cooling housing. If saline was used for cooling during surgery, use distilled water to rinse the housing prior to draining.
- If using a dishwasher, place handpiece in a vertical position (motor up) to allow water drainage.
- **Sterilize the motor assembly immediately after cleaning.**

Powerforma® Handpiece

- **DO NOT** immerse the handpiece.
- **IMPORTANT NOTE:** These procedures are critical to continued optimal performance. O.R. Personnel should be familiar with the cleaning solutions and should use them routinely each time the handpiece is used.

CLEANING CAUTIONS

- Always hold the handpiece with the nose pointing down to prevent any moisture from reaching the motor.
- If using a dishwasher, place handpiece in a vertical position (motor up) to allow water drainage.
- **DO NOT LUBRICATE, SOAK, WASH OR SUBMERGE** the handpiece in detergent or any solution.
- Always keep the handpiece as dry as possible to prevent corrosion, especially during sterilization and storage.

CLEANING HANDPIECE BUR CHUCK

- Set the maximum speed to the 25% setting.
- CAUTION: Cleaning at speeds over 25% may damage handpiece.
- Remove the bur and insert only the nose of the handpiece into 1 oz. of an enzymatic detergent solution.
- Run the handpiece for approximately 30 seconds.
- Rinse the bur chuck by running the handpiece in distilled water for approximately 30 seconds.
- Dry the inside of the bur chuck with a chuck brush (pipe cleaner, REF # 3112500).
- Wipe off the handpiece with disinfectant and a soft cloth to remove blood and particles.
- Cover the nose of the handpiece with the nose protector. This attachment shields the chuck and irrigation tip.
- **Sterilize the handpieces immediately after cleaning.**

CLEANING TUBING

- Using distilled water, flush saline from reusable tubing and the tubing that runs through the handpiece. Clear the tubing of all water by running in the pump until all water is removed. Autoclave the reusable tubing along with the handpiece.
- **Sterilize the tubing, along with the handpiece, immediately after cleaning.**

  OR
- If using disposable tubing, flush the portion of tubing that runs through the handpiece, and clear it of all water. Then discard the disposable tubing.
- Use a fresh tubing set for the next surgical procedure.

CLEANING (continued)

Skeeter® Handpiece

- The handpiece may be cleaned and carefully rinsed with an enzymatic detergent. DO NOT FULLY IMMERSE OR ULTRASONICALLY CLEAN THIS INSTRUMENT. The cannulated needle nose should be cleaned after each use and prior to sterilization by immersing the distal end of the handpiece in an enzymatic detergent solution to the level of the Bur Release Button. DO NOT USE ANY CLEANING INSTRUMENTS IN THE CANNULATED SHAFT OF THE HANDPIECE.
- To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.

Rinsing:

- Immerse the distal end of the handpiece in distilled water up to the Bur Release Button and use a gentle swirling motion to flush away residual cleaning solution. Avoid water accumulation in the motor housing by shaking excess water droplets out with a downward motion.

Lubrication:

- Silicone spray should be sprayed into the cannulated shaft of the handpiece prior to sterilization. Apply silicone spray until surplus silicone lubricant is noted on the outside of the Bur Release Button. Wipe away excess lubricant from the handpiece. Following this procedure will insure that the bur release mechanism is well lubricated for proper functioning.
- **Sterilize the handpieces immediately after cleaning.**

Oto-Flex Burs

Cleaning:

- The Skeeter® Ultra-Lite Oto-Tool Systems accepts Oto-Flex Burs. All Oto-Flex Burs may be cleaned either by using an enzymatic detergent or by ultrasonic means. Rinse with distilled water to remove cleaning solution residues and allow burs to dry. Following cleaning, apply a light coating of silicone spray in the following manner: grasp the PTFE bearing and rotate the bur to assure application of the silicone spray inside the bearing.

Maintenance:

- During routine use normal wear may become evident on the bur and bur shaft. Examine burs under magnification for evidence of wear following each cleaning. Minor bowing of the bur shaft may be straightened by using the fingers to rub and pull on the small shaft. Care should be exercised not to crimp or bend the small shaft during handling or when straightening the shaft. Frequent replacement of burs is recommended to assure optimum cutting performance and PTFE bearing concentricity. Burs exhibiting the following conditions should be replaced: 1) nicks on cutting surfaces, 2) noticeable wear on PTFE bearings, 3) severe bends or crimps on bur shaft, or 4) bur not running concentrically.

XPS® Disposable Blades and Burs

- **Do Not** reuse. Remove and discard following local regulations for proper disposal of contaminated materials.

Medtronic Xomed Reusable Burs for Mastoid Drilling

CAUTION

- Burs should be removed from the handpiece for sterilization and drying.
- Monitor bur edges by viewing under microscope or magnifying glass. Dull burs increase pressure on the handpiece. The motor may overheat and be damaged if continually overloaded.

Cleaning:

1. Promptly and thoroughly rinse burs with deionized water after each use.
2. Soak in lukewarm*, mild* enzymatic detergent, and deionized water for a minimum of two minutes. Clean ultrasonically in a lukewarm* solution of mild* detergent and deionized water for at least 30 seconds. Rinse thoroughly with deionized water and wipe dry.
   (*less than 43°C; pH 7.0 - 8.5)

Additional cleaning methods:

- Presoaking in 3% hydrogen peroxide.
- Additional thorough scrubbing of burs with a soft instrument brush while submerged in cleaning solution may be warranted to remove blood and tissue.

STERILIZATION

The following cycles are compatible with the each handpiece as listed below; however, **it is the responsibility of each health care facility to validate the sterilization process with their particular equipment and procedures to assure sterility.**

WARNINGS

- **DO NOT** modify accessories used with any handpiece.
- Insertion of metal objects in blade or bur window may cause the blade or bur to break leaving fragments in the wound which may be difficult to remove.
- Bending or prying may break the blade or bur, causing harm to patient or staff.

PRECAUTIONS

- **DO NOT** immerse the handpieces, as damage may result.
- After sterilizing, check electrical connectors for moisture. If moisture is present do not operate, as damage may result. Do not operate or store the handpiece unless a drying cycle has been performed.
- **DO NOT** cold soak sterilize the handpiece in glutaraldehyde. This will void the warranty.
- Regardless of which type of steam sterilization is used, it is important that all electrical connectors of the handpiece be free of any moisture in the internal connection features. Damage may result to the instrument if it is operated with moisture in the electrical connectors. Do not operate or store the handpiece unless a drying cycle has been performed.
- Remove the handpiece from the sterilizer immediately after the sterilization cycle is complete.
- Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149° C (300° F). Heating above 149° C (300° F) may damage the handpiece and will void the warranty.
- **DO NOT** use organic solvents such as acetone or isopropyl alcohol to clean the bur chuck.
- Use only a mildly alkaline, low-sudsing detergent (Medtronic Xomed Cleaning Solution is recommended) and distilled water for cleaning after every case or as required.
- Remove the bur from the Drill handpieces before sterilization.
- Store in a clean dry place.
- **DO NOT** clean handpieces in ultrasonic cleaner or allow them to be fully immersed in any soaking solution. These procedures my result in damaging the handpieces beyond repair.
- **DO NOT** attempt to bend needle nose or effect repairs to either system.
- Remove the bur from the handpiece before sterilization.
- Sterilize immediately after cleaning. DO NOT STORE UNLESS A DRYING CYCLE HAS BEEN PERFORMED.
- Always wrap the electrical cord carefully inside the sterilizer tray during sterilization to prevent damage to the cord when closing the tray lid.
- Regardless of which type of steam sterilization is used, **it is extremely important that the handpiece is rapidly and completely dried before it is stored**. If a vacuum drying cycle is not used following steam sterilization, moisture may be trapped within the handpiece causing corrosion and residue deposits, resulting in premature wear and a reduction in the functional life expectancy of the handpiece.

XPS® 3000 Console

- **DO NOT** attempt to sterilize.

Footswitches

- **DO NOT** attempt to sterilize.

STERILIZATION (continued)

XPS® StraightShot® M4, StraightShot® Magnum® II and StraightShot® Magnum® Handpieces

Steam Sterilization — Gravity: Wrapped — 121°C to 123°C (250°F to 254°F) for 40 minutes plus 8 minutes minimum vacuum drying cycle.
Steam Sterilization — Pre-Vac: Wrapped — 132°C to 135°C (270°F to 275°F) for 6 minutes minimum steam cycle, plus 8 minutes minimum vacuum drying cycle.
Flash Autoclaving: AORN recommends for unwrapped flash cycles, a minimum of 10 minutes at 132°-135°C (270°-275°F) in a gravity-displacement sterilizer, or 4 minutes at 132°-135°C (270°-275°F) in a pre-vacuum sterilizer. Medtronic Xomed recommends a minimum 8 minutes vacuum drying cycle.
Caution: Failure to perform the recommended vacuum drying cycle may result in premature wear of the handpiece.
STERRAD Sterilization: STERRAD compatible.
Ethylene Oxide: EtO compatible with the following cycle parameters:

Preconditioning (in-chamber) Parameters	Sterilization Parameters
Temperature: 54°C to 55°C (129°F to 131°F)	Temperature: 54°C to 55°C (129°F to 131°F)
Relative Humidity: 35% minimum	Relative Humidity: 35% minimum
Vacuum Set Point: 1.3 psia	Chamber EtO Concentration: 575 to 625 mg/L
Preconditioning Time: 30 minutes	Exposure Duration: 2 hours

Minimum aeration period of twenty-four (24) hours at room temperature is recommended. Follow parameters provided by the manufacturers of sterilizer equipment for each cycle. Alternately, mechanical aeration for twelve (12) hours at 50°C (122°F), or 8 hours at 60°C (140 °F) is acceptable.

No matter which type of steam sterilization is used, **it is extremely important that the handpiece be rapidly and completely dried before storage** to prevent corrosion and residue deposits in the bearings and motor.

Visao™ High-Speed Otologic Drill, Xcalibur® Hi-Torque Motor, Xcalibur® Hi-Speed Motor, Xcalibur® Handpiece Attachments, and Powerforma® Handpieces

Steam Sterilization — Gravity: Wrapped — 121°C to 123°C (250°F to 254°F) for 40 minutes plus 8 minutes minimum vacuum drying cycle.
Steam Sterilization — Pre-Vac: Wrapped — 132°C to 135°C (270°F to 275°F) for 9 minutes minimum steam cycle, plus 8 minutes minimum vacuum drying cycle.
Flash Autoclaving: AORN recommends for unwrapped flash cycles, a minimum of 10 minutes at 132°-135°C (270°-275°F) in a gravity-displacement sterilizer, or 4 minutes at 132°-135°C (270°-275°F) in a pre-vacuum sterilizer. Medtronic Xomed recommends a minimum 8 minutes vacuum drying cycle.
Warning: Remove cleaning plug from the front of the motor assembly during sterilization.
Caution: Failure to perform the recommended vacuum drying cycle may result in premature wear of the handpiece.
STERRAD Sterilization: STERRAD compatible. **(DO NOT USE STERRAD ON THE VISAO™ OR XCALIBUR® IRRIGATION SLEEVE, THE VISAO™ OR XCALIBUR® EXTENDED BUR GUARDS WITH IRRIGATION, OR THE POWERFORMA® HANDPIECE.)**
Ethylene Oxide: Handpieces are EtO compatible (see Preconditioning/Sterilization Parameters above). See steam sterilization instructions for the reusable tubing used with the Powerforma Handpieces. Minimum aeration period of twenty-four (24) hours at room temperature is recommended. Follow parameters provided by the manufacturers of sterilizer equipment for each cycle. Alternately, mechanical aeration for twelve (12) hours at 50°C (122 °F), or 8 hours at 60°C (140 °F) is acceptable.

No matter which type of steam sterilization is used, **it is extremely important that the handpiece be rapidly and completely dried before storage** to prevent corrosion and residue deposits in the bearings and motor. Use of a minimum 8 minutes vacuum drying cycle is recommended.

STERILIZATION (continued)

Skeeter® Handpiece

Gravity:
Wrapped; 132°C to 135°C (270°F to 275°F) for 25 minutes, plus 8 minutes minimum vacuum drying cycle.
OR
Wrapped; 121°C to 135°C (250°F to 275°F) for 30 minutes, plus 8 minutes minimum vacuum drying cycle.
Pre-Vac: Wrapped; 132°C to 135°C (270°F to 275°F) for 6 minutes minimum steam cycle, plus 8 minutes minimum vacuum drying cycle.
Flash Autoclaving: Unwrapped: A minimum of 3 minutes at a maximum temperature of 140°C (284°F) advised only when emergency action is required (e.g.; a break in sterile technique). Immediately following the surgical procedure, the handpiece should be thoroughly cleaned and sterilized with a drying cycle, preferably with vacuum.
Ethylene Oxide: EtO compatible (see Preconditioning/Sterilization Parameters above). Minimum aeration period of twenty-four (24) hours at room temperature is recommended. Follow parameters provided by the manufacturers of sterilizer equipment for each cycle. Alternately, mechanical aeration for twelve (12) hours at 50°C (122°F), or 8 hours at 60°C (140°F) is acceptable.
STERRAD Sterilization: STERRAD compatible.

No matter which type of steam sterilization is used, **it is extremely important that the handpiece be rapidly and completely dried before storage** to prevent corrosion and residue deposits in the bearings and motor.

Oto-Flex Burs

Medtronic Xomed drill systems and burs may be sterilized by any one of several properly validated methods. The method of sterilization selected by individual health care facilities is dependent upon the capabilities of each facility. **IT IS THE USER'S RESPONSIBILITY TO VALIDATE THE STERILIZATION PROCESS TO ENSURE STERILITY**. The following guidelines are recommended and are compatible with the burs.

STEAM STERILIZATION
Gravity:
Wrapped; 132°C to 135°C (270°F to 275°F) for 25 minutes, plus 8 minutes minimum vacuum drying cycle.
OR
Wrapped; 121°C to 123°C (250°F to 253°F) for 30 minutes, plus 8 minutes minimum vacuum drying cycle.
Prevac: Wrapped: 132°C to 135°C (270°F to 275°F) for 6 minutes minimum steam cycle, plus 8 minutes minimum vacuum drying cycle.
Flash Autoclaving: Unwrapped**:** A minimum of 3 minutes at a maximum temperature of 140°C (284°F) ADVISED ONLY WHEN EMERGENCY ACTION IS REQUIRED (e.g., a break in sterile technique). IMMEDIATELY following the surgical procedure, the bur should be thoroughly cleaned and sterilized with a drying cycle, preferably with vacuum. Flash sterilization should follow *2000 AORN Standards, Recommended Practices, and Guidelines.*
Ethylene Oxide Sterilization: EtO compatible (see Preconditioning/Sterilization Parameters above). A minimum aeration period of twenty-four (24) hours is recommended following EO sterilization. The parameters established by the sterilizer equipment manufacturer should be carefully followed for each cycle.
STERRAD Sterilization: STERRAD compatible.

XPS® Disposable Blades and Burs

- Limit use of disposable blades, burs and tubing to only one time, unless otherwise marked. Do not attempt to sterilize disposable parts. Disposable, single-use parts are packaged sterile and are **not** intended for repeated use.

STERILIZATION (continued)

Medtronic Xomed Reusable Burs for Mastoid Drilling

- Before sterilization, carefully inspect the bur tips, bur flutes or diamond tips under a microscope or magnifying glass for any irregularities or eccentricities. **Discard any burs which show signs of damage or wear.**
- **DO NOT COLD SOAK IN GLUTARALDEHYDE, CHLORINE, OR AMMONIUM SOLUTIONS OR DRY HEAT STERILIZE AS DAMAGE TO THE BURS MAY OCCUR.**

The following cycle has been validated by Medtronic Xomed and is compatible with the products; however, it is the responsibility of each health care facility to validate the sterilization process with their particular equipment and procedures to assure sterility.
Steam Sterilization – Gravity: Wrapped – 121°C to 123°C (250°F to 253°F) for 40 minutes plus 8 minutes minimum vacuum drying cycle.
Steam Sterilization – Pre-Vac: Wrapped - 132°C to 135°C (270°F to 275°F) for 9 minutes minimum steam cycle, plus 8 minutes minimum vacuum drying cycle.

STERILIZATION REFERENCES

- AAMI Standards and Recommended Practices — Volume 1.1: *Sterilization; Part 1-Good Hospital Practices,* Association for the Advancement of Medical Instrumentation, 1996. PH: 703-525-4890.
- AAMI Standards and Recommended Practices — Volume 1.2: *Sterilization; Part 2-Hospital Equipment and Industrial Process Control,* Association for the Advancement of Medical Instrumentation, 1996. PH: 703-525-4890.
- *2000 AORN Standards, Recommended Practices, and Guidelines* (Denver: AORN (Association of periOperative Registered Nurses), 2000). PH: 303-755-6300.
- EN 550 *Sterilization of Medical Devices, Validation and Routine control of EtO Sterilization.*
- EN 554 *Sterilization of Medical Devices, Validation and Routine control of Sterilization by Moist Heat.*

TROUBLESHOOTING

SYSTEM MALFUNCTIONS

CODE	ERROR
2	Handpiece Fault
3	+5V Failure
4	+12V Failure
5	48V Failure
7	Watchdog Timer Failure

IF ..... Any of the above error codes are displayed...
- Cycle power; i.e. turn the power off and back on.
- Call Customer Service.

IF ..... Console lights fail to illuminate...
- Ensure that the power switch on the rear of the console is in the "|" position.
- Inspect power cord connections, and ensure that power cord is firmly seated.
- Inspect two fuses next to the power connector, and if a fuse appears to be blown, remove and replace it with a 4.0A, 250V, Type F fuse.

BLADE OR BUR MALFUNCTIONS

IF ..... Upon inspection, blade or bur appears to be damaged or defective...
- Remove and replace defective blade or bur.

IF ..... Blade or bur is not firmly seated...
- Pull back locking collar and reseat the blade or bur.

IF ..... Blade opening is obstructed...
- Remove blade from surgical site and submerse the blade tip in sterile water with suction connected to the handpiece to evacuate the obstruction, or use stylette to clear blade. The suction tube may be removed from the handpiece and inserted over the end of the blade and blade activated to evacuate the obstruction from the tip of the blade.

IF ..... Blade or bur is leaking irrigant...
- Check for proper blade/bur insertion by pulling back locking collar, and reseating blade/bur.
- Check blade for obstruction. If visible, evacuate obstruction by one of the above methods.
- Inspect suction connection on handpiece and at suction cannister, and if suction tubing is disconnected, connect it.
- Remove and inspect suction tubing, and if obstructed, remove obstruction.

IF ..... Blade or bur continues to malfunction...
- Remove and replace blade or bur.
- Call Customer Service.

IF ..... Burs wobble in Xcalibur® or Powerforma® Handpieces...
- Reduce handpiece operating speeds.
- Use burs that are rated for the console speed selected.
- If necessary, use extended bur guards with Xcalibur® drills for 64 mm and 75 mm burs.
- Operate handpiece at 50% of full speed for 64 mm and 75 mm burs.
- Select a new bur.

VISAO™ OTOLOGIC DRILL / XPS® STRAIGHTSHOT® M4 MICRODEBRIDER / STRAIGHTSHOT® MAGNUM® / STRAIGHTSHOT® MAGNUM® II / POWERFORMA® / XCALIBUR® / SKEETER® HANDPIECE MALFUNCTIONS

IF ..... Console lights illuminate but handpiece fails to rotate...

- Inspect handpiece cable connections, and ensure that handpiece cable connector is firmly seated.
- If handpiece continues to malfunction, call Customer Service.

IF ..... Handpiece defaults to incorrect speed...

- Dry handpiece per sterilization cycle recommendations and try again. If handpiece continues to malfunction, call Customer Service.

FOOTSWITCH MALFUNCTIONS

IF ..... Console displays operation speed percentages and handpiece does not operate properly...

- Inspect footswitch cable connection, and ensure that footswitch cable connector is firmly seated.

IF ..... Footswitch continues to malfunction...

- Disconnect footswitch and operate handpiece with “Manual Start Stop” button on the rear console.
- Call Customer Service.

IF ..... Handpiece operates without activating the footswitch...

- Call Customer Service.

LIMITED WARRANTY

A. This LIMITED WARRANTY provides assurance for the customer who purchases an XPS® Model 3000 System (hereinafter the "Product") that should the Product fail to function to Medtronic Xomed's published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product, 90 days from date of shipment for refurbished or used Product), Medtronic Xomed will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Xomed or from its affiliate or its authorized distributor or representative.

B. To qualify for this LIMITED WARRANTY, the following conditions must be met:
   (1) The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
   (2) The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
   (3) Medtronic Xomed must be notified in writing within thirty (30) days following discovery of a defect.
   (4) The Product must be returned to Medtronic Xomed within thirty (30) days of Medtronic Xomed receiving notice as provided for in (3) above.
   (5) Upon examination of the Product by Medtronic Xomed, Medtronic Xomed shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Xomed or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.

C. This LIMITED WARRANTY is limited to its express terms. **THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** In no event shall Medtronic Xomed be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.

D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

CAUTION

Applicable law may restrict the sale, distribution or use of this device to, by or on the order of a licensed medical practitioner.

RETURNS AND/OR REPAIRS

Contact Medtronic Xomed Customer Service at (800-874-5797) to obtain a Return Goods Authorization number (RGA#) prior to shipping the Product to Medtronic Xomed. Please have the original invoice number or purchase order number available to assist in verifying warranty information. The RGA# should be prominently displayed on the box and included on all paperwork enclosed with the return and/or repair. All Product returned to Medtronic Xomed should be safely packed in protective wrapping.

Customer must supply the Purchase Order number; the correct shipping and billing address; and either a completed Repair Order Form or a statement of the problem or reason for return.

TECHNICAL SPECIFICATIONS

HANDPIECES - XPS® StraightShot® M4 Microdebrider / StraightShot® Magnum® II / LandmarX® Magnum® II / XPS® StraightShot® III

Part No.

1898200T	XPS® StraightShot® M4 Microdebrider
1897200	StraightShot® Magnum® II Handpiece
1897200T	LandmarX® Magnum® II Handpiece
1897201	XPS® StraightShot® III Handpiece (Japan only)

Speed

500-5,000 rpm oscillate
500-12,000 rpm forward

Size

14.3 cm length x 1.8 cm width (1898200T)
17 cm length x 1.6 cm diameter (1897200, 1897200T, and 1897201)

Weight

228 g	1898200T
240 g	1897200
254 g	1897200T
240 g	1897201

Duty Cycle

The XPS® StraightShot® M4, StraightShot® Magnum® II, LandmarX® Magnum® II, and XPS® StraightShot® III Handpieces under full load are rated for intermittent operation per the following:
Maximum On Time 60 seconds
Minimum Off Time 30 seconds

VISAO™ AND XCALIBUR® DRILLS

Part No.

3334800	Visao™ High-Speed Otologic Drill
3334800T	Visao™ High-Speed Otologic Drill, IGS Trackable
3333700	Xcalibur® Straight Hi-Torque Handpiece Attachment
3333705	Xcalibur® Straight Hi-Speed Handpiece Attachment
3333750	Xcalibur® Angled Hi-Torque Handpiece Attachment
3333755	Xcalibur® Angled Hi-Speed Handpiece Attachment
3333840	Xcalibur® Hi-Speed Motor Assembly, Water-Cooled
3333850	Xcalibur® Motor Assembly (Hi-Torque)

Speed

10,000-80,000 rpm forward/reverse, Visao™ High-Speed Otologic Drill, Water-Cooled (3334800 and 3334800T)
10,000-52,000 rpm forward/reverse Xcalibur® Hi-Torque Motor (3333850)
10,000-80,000 rpm forward/reverse, Xcalibur® Hi-Speed Motor, Water-Cooled (3333840)

Size

16.0 cm length x 2.0 cm diameter	3334800
16.0 cm length x 2.0 cm diameter	3334800T
10.5 cm length x 2.0 cm diameter	3333700
9.8 cm length x 2.0 cm diameter	3333705
11.7 cm length x 2.0 cm diameter	3333750
11.2 cm length x 2.0 cm diameter	3333755
12.0 cm length x 2.0 cm diameter	3333840
12.0 cm length x 2.8 cm diameter	3333850

Weight

148 g	3334800
148 g	3334800T
58 g	3333700

VISAO™ AND XCALIBUR® DRILLS (continued)

59 g	3333705
78 g	3333750
80 g	3333755
175 g	3333840
195 g	3333850

Duty Cycle The Visao™ High-Speed Otologic Drill and Xcalibur® Drill under full load are rated for intermittent operation per the following:
Maximum On Time 60 seconds
Minimum Off Time 30 seconds

MPS® POWERFORMA® DRILL

Part No.

3327700	Straight Handpiece
3327750	Angled Handpiece

Speed 10,000-52,000 rpm forward/reverse

Size

19.1 cm length x 2.9 cm diameter	3327700
19.7 cm length x 2.9 cm diameter	3327750

Weight

165 g	3327700
182 g	3327750

Duty Cycle The Powerforma® Handpieces under full load are rated for intermittent operation per the following:
Maximum On Time 60 seconds
Minimum Off Time 30 seconds

SKEETER® ULTRA-LITE OTO-TOOL

Part No. 3055601

Speed 12,000 rpm forward

Size 17 cm length x 1.6 cm diameter

Weight 57 g

Duty Cycle Continuous run

CONSOLE

Part No.

1897101	XPS® Model 3000 Console With Irrigation (one pump)
1897102	XPS® Model 3000 Console With Coolant and Irrigation (two pumps)

Electrical Input Power 100-240 VAC, 47-63 Hz, 4 A

Size 20 cm Width x 28 cm Height x 18.5 cm Depth (1897101 and 1897102)

Weight

4.5 kg	1897101
5.0 kg	1897102

Class Class I Medical Device per EN 60601-1

XPS® MULTIFUNCTION FOOTSWITCH

Part No. 1895400

Size 18 cm Length x 18.5 cm Width x 6.3 cm Height

Weight 1.8 kg

Protection Against Water Ingress IPX8

XPS® MULTIFUNCTION FOOTSWITCH, SINGLE PEDAL

Part No. 1895420

Size 18 cm Length x 18 cm Width x 3.8 cm Height

Weight 1.8 kg

Protection Against Water Ingress IPX8

XPS® SINGLE FUNCTION FOOTSWITCH

Part No. 1895410

Size 11.5 cm Length x 8.9 cm Width x 5.6 cm Height

Weight 0.8 kg

Protection Against Water Ingress IPX8

COMPLIANCE

Meets requirements of the following standards:
EN 60601-1:1990 with A1 and A12:1993, A2: 1995 and A13:1996
IEC 60601-1, Second Edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995
UL 2601-1 2nd Ed., 1997
CAN/CSA-C22.2 No. 601.1-M90
IEC 60601-1-2:2001
EN 60601-1-2:2001

EC Certification: EC Cert. No. G1 00 12 41921 002
CB Test Certificate: US/801/ITS-M1

Guidance and manufacturer's declaration – electromagnetic immunity - Part I

Guidance and manufacturer's declaration – electromagnetic immunity - Part I			
The XPS® 3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the XPS® 3000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 % UT for 0.5 cycle 40 % UT for 5 cycles 70 % UT for 25 cycles <5 % UT for 5 sec	<5 % UT for 0.5 cycle 40 % UT for 5 cycles 70 % UT for 25 cycles <5 % UT for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the XPS® 3000 requires continuous operation during power mains interruptions, it is recommended that the XPS® 3000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The XPS® 3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the XPS® 3000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The XPS® 3000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The XPS® 3000 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the XPS® 3000

Recommended separation distances between portable and mobile RF communications equipment and the XPS® 3000

The XPS® 3000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the XPS® 3000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the XPS® 3000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum power of transmitter W	**Separation distance according to frequency of transmitter** (meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity - Part II

Guidance and manufacturer's declaration – electromagnetic immunity - Part II

The XPS® 3000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the XPS® 3000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the XPS® 3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V / m 80 MHz to 2.5 GHz	3 V / m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the XPS® 3000 is used exceeds the applicable RF compliance level above, the XPS® 3000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the XPS® 3000.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED ENVIRONMENTAL CONDITIONS

Operating
Temperature: ..... +10°C to +40°C (+50°F to +104°F)
Humidity: ..... 30% to 75% RH
Barometric Pressure: ..... 700 - 1060 hPa

Storage
Temperature: ..... -40°C to +70°C (-40°F to +158°F)
Humidity: ..... 10% to 100% RH
Barometric Pressure: ..... 500 - 1060 hPa

Medtronic Xomed, Inc.
Jacksonville, FL 32216-0980 U.S.A.

68E3524 M 02/2013

REF 1897851